

EPA Registration No.
82572-1
vol. 3

MATERIAL TO BE ADDED TO JACKET

REG #: 82572-1

Description: acceptance of conditional data, label amendment

if applicable, check all that are attached:		Send to CSC
<input checked="checked" type="checkbox"/>	new stamped accepted label	
<input type="checkbox"/>	new CSF	
<input type="checkbox"/>	notification	
<input type="checkbox"/>	other:	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer: John Fournier Date: 11/16/2011

Phone: (703) 308-0169 Division: BPPD

NOV 16 2011

Desert King Chile
c/o Amy Plato Roberts, Senior Regulatory Consultant
Technology Sciences Group, Inc.
712 Fifth Street, Suite A
Davis, CA 95616

Subject: Submission of product performance data to satisfy term of registration
Quillaja Extract
EPA Reg. No.: 82572-1
Your submission dated July 22, 2011
Decision Number: 452381

Dear Ms. Roberts:

The submission of the product performance studies, referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has been received and reviewed, and the studies are acceptable. You have satisfied OCSP guideline studies 810.1000 as required and outlined in your Notice of Pesticide Registration dated July 14, 2007. Enclosed is the new Notice of Pesticide Registration for your product, as well as a stamped approved master label. Should you have any questions, you may contact John Fournier directly at (703) 308-0169 or via email at fournier.john@epa.gov.

Sincerely,



Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

CONCURRENCES

SYMBOL	▶ 7511P							
SURNAME	▶ Fournier							
DATE	▶ 16 Nov 11							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number:

82572-1

Date of Issuance:

NOV 16 2011

Term of Issuance:

Unconditional

Name of Pesticide Product:

Quillaja Extract

NOTICE OF PESTICIDE:

☒ Registration☐ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Desert King Chile
c/o Amy Plato Roberts, Senior Regulatory Consultant
Technology Sciences Group, Inc.
712 Fifth Street, Suite A
Davis, CA 95616

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA Sec. 3(c)(5) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Date:

NOV 16 2011

W. Michael McDavit, Associate Director
Biopesticides and Pollution Prevention Division

EPA Form 8570-6

CONCURRENCES

SYMBOL	7511P	7511P						
SURNAME	Fournier	Harris						
DATE	16 Nov 11	11-16-11						

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

Master Label

Sublabel A: Agricultural Use

Sublabel B: Home Garden and Lawn Use

Optional Label Claims

Quillaja Extract

[Alternate brand names: QL Agri, QL Agri35]

Active Ingredient:

*Saponins of Quillaja saponaria.....8.60%

Other Ingredients: 91.40%

Total: 100.00%

*bidesmosidic derivatives of quillajic acid substituted with a trisaccharide at C-3 and an oligosaccharide in C-28

Manufactured for:

Desert King Chile

77 Antonio Bellet, Suite 401

Providencia, Santiago

Chile

EPA Reg. No.: 82572-1

EPA Est. No.: XXXXX-XX-XX

Net Contents: XX Gallons

Batch Code: XXX

ACCEPTED

NOV 16 2011

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 82572-1

Quillaja Extract; EPA Reg. No. 82572-1

Label changes add directions for use and updated container disposal (PRN2007-4)

MASTER LABEL - Version (12) - November 14, 2011

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Sublabel A: Agricultural Use

Quillaja Extract

A Bio-Pesticide

*For Control of Plant Parasitic Nematodes and Plant Parasitic Fungi
in Vineyards, Orchards, Field Crops, Turf and Ornamentals*

Active Ingredient:

*Saponins of Quillaja saponaria.....8.60%

Other Ingredients:91.40%

Total:100.00%

*bidesmosidic derivatives of quillajic acid substituted with a trisaccharide at C-3 and an oligosaccharide in C-28

KEEP OUT OF REACH OF CHILDREN

WARNING - ADVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

See back side for additional precautionary statements.

Manufactured for:
Desert King Chile
77 Antonio Bellet, Suite 401
Providencia, Santiago
Chile

EPA Reg. No.: 82572-1
EPA Est. No.: XXXXX-XX-XX

Net Contents: XX Gallons
Batch Code [Lot No.]: XXX

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye damage. Do not get in eyes or on clothing. Harmful if swallowed or absorbed through skin. Avoid contact with skin.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Protective eyewear
- Chemical-resistant gloves made of any waterproof material
- Shoes and socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Never apply material so as to contaminate eating or drinking area.
- Remove clothing/PPE immediately if product gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the Agency responsible for pesticide regulations.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label about personal protective equipment and the restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas without protective clothing during the restricted-entry interval (REI) of 24 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Chemical-resistant gloves made of any waterproof material
- Protective eyewear
- Shoes and socks

NON - AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of the product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural and ornamental plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

Mixing:

Fill tank with water to at least half full, then add recommended dosage of Quillaja Extract directly to the tank and continue filling. Agitation should be minimized in the tank (shut off paddle agitation if possible) to prevent foaming. To reduce foaming, an agricultural defoamer may be added to the tank mix. However, Quillaja Extract foam is very water soluble, will form a true solution, and should not be a concern for settling in the tank. Apply solution within three hours of mixing.

Compatibility:

Quillaja Extract is a water soluble botanical extract. It is physically compatible with most water based pesticides and liquid fertilizers providing the pH of the final solution is in a pH range of 3 to 8. Do not apply Quillaja Extract with any other product before testing for physical and chemical compatibility. To determine compatibility, pour the recommended proportions of the products into a suitable container, mix and wait for 30 minutes. If product remains mixed, it is considered physically compatible.

Not all tank mix combinations have been tested with this product. If compatibility of this product with another product is unknown, the mixture should be tested on a small scale.

Read and carefully observe the most restrictive of the labeling limitations and precautions of all product labels used in the tank mix. This product has properties similar to wetting agents and may enhance activity of some products as a wetting agent.

Application Methods: Consider the high solubility of this product when choosing a method of application and timing.

Foliar spray application (for powdery mildew): Apply by ground equipment to ensure complete and thorough coverage of foliage and/or crop. Contact of the disease organisms is essential for curative control.

Ground spray application (for nematodes and root rot): After area to be treated has been irrigated to field capacity, apply with a band or broadcast type sprayer, such as flat-fan or hollow cone nozzle tip system, to the soil surface. After application has been made it will be necessary to water with either drip, above ground sprinklers or reduced amount of furrow irrigation. Do not over irrigate following application of this product. Do not use flood irrigation to apply this product into the ground. Over irrigation will move the desired concentration of the product too quickly past the targeted root zone.

For ground sprayer application in orchards or around trees, begin application next to the tree trunk and spray at least 50% of soil area or the area under the canopy of the tree, whichever is greatest.

Shank injection application (for nematodes): After area to be treated has been irrigated to field capacity, apply by shank injection to areas where roots are present. Use a sufficient number of injectors to cover area to be treated. If shank application is applied at the root zone, minimal irrigation is required to assure that product covers root zone.

Chemigation application (for nematodes and root rot): Apply Quillaja Extract through the following types of systems. Do not apply this product through any other type of irrigation system.

- Low volume (ground or underground) drip, drip tape, strip tubing, micro-jet sprinklers, mini-sprinklers;
- Sprinkler including center pivot, lateral move, end tow, side (wheel) roll, solid set, or hand move;
- Furrow.

Check irrigation system and emitters to ensure all systems are operating normally before injecting Quillaja Extract. Lack of effectiveness or crop injury can result from non-uniform distribution of treated water.

If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers, chemigation experts or the Distributor of this product.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place. In addition, check local and state regulations regarding pesticide injection into public water systems.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Maintain the system's operating pressure low enough to prevent fogging and/or misting during applications. Inject Quillaja Extract into the irrigation system after the filter(s) or shut off the automatic back flush system in order to avoid back flushing of treated water.

Systems using a gravity flow pesticide dispensing system must meter the product into the water at the head of the field and downstream of the hydraulic discontinuity, such as a drop structure or weir box, to decrease potential for water source contamination from backflow if water flow stops.

Systems using a pressurized water and pesticide injection system must meet the following requirements:

- The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
- The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of material that are compatible with pesticide and capable of being fitted with a system interlock.

It is highly recommended that the soil be irrigated to field capacity (down to two feet of soil) before pesticide application. For best results, inject Quillaja Extract into the irrigation line in the last quarter of the irrigation time. Continue irrigation until all lines are flushed. Maintain irrigation for enough time to assure this product has penetrated down into the targeted root zone. Do not over irrigate after applying this product. If excessive watering occurs immediately following application, this product may move down past the desired root zone due to its high water solubility. Do not irrigate for at least 24 hours following application of this product. Pest injury to the crop may result from uneven distribution of this product during application.

Do not allow air in the line prior to injecting Quillaja Extract. The product's density will cause swelling of the line due to foam formation and prevent uptake of material. If a pesticide supply tank is used, follow directions listed under "Mixing" above. There generally will be some level of foam at the base of the wetted area until it dissolves (usually within 30 minutes after application, depending on temperature and amount of water following application).

If applied in heavy rainfall areas, avoid application during rain or when rain is forecasted within the next 24 hours that may exceed movement of this product past targeted root zone. Do not apply when wind speed favors drift beyond the areas intended for treatment

Application Rates for Control of Nematodes

Quillaja Extract lessens the damage caused by nematodes and increases crop yields. To control/suppress plant parasitic nematodes, apply Quillaja Extract to the full irrigated zone. For row crops, the irrigated zone is 30-50% of the row area. For orchards or around trees, apply from tree trunk to drip-line to cover at least 50% of soil area or the area under the canopy of the tree, whichever is greatest. Single applications should be made in the spring just prior to or during root flush, and again in the fall after harvest. For best results, multiple applications may be made in the spring, followed by a single application in the fall after harvest. Use Quillaja Extract in combination with other nematode control products in an IPM program to achieve season-long control of target pests.

Crop	Remarks
<p>Berries: (Not for Use in California) Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Huckleberry, Loganberry, Raspberry (black and red)</p> <p>Citrus: Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo</p> <p>Grapes (raisin, table, wine)</p> <p>Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)</p> <p>Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince</p> <p>Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune</p>	<p>On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.</p>

Cole Crops:

Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables:

Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables:

Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables:

Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Strawberry

Apply 1-7 days preplant to the planting zone. Apply centered on the top of the row on pre-wetted soil. Follow with water to assure penetration of the product into the root zone.

On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.

On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.

For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.

<p>Bulb Vegetable: Garlic, Leek, Onion (including dry bulb, green and Welch), Shallot</p> <p>Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Ginseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)</p> <p>Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals</p>	<p>Apply prior to planting to row area to be planted. Apply centered on the top of the row on pre-wetted soil. Follow with water to assure penetration of the product into the root zone.</p> <p>On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.</p>
<p>Turfgrass Ornamental lawns, Golf courses, Sod farms</p> <p>For control of <i>Anguina pacifica</i> nematode only.</p>	<p>Apply 9 fl.oz. in 3-7 gallons water per 1,000 sq.ft. (equivalent to 3 gallons in 130-300 gallons water per acre) using a sprayer with a pressure nozzle tip applicator sufficient to penetrate into the lower part of the turf leaves where <i>Anguina pacifica</i> nematode galls are formed. Do not exceed a concentration of 1.5% solution of Quillaja Extract in any application.</p> <p>Repeat applications every 5-10 days. Additional applications to break the life cycle of the nematode should be repeated 2-4 times within 60 days to significantly reduce this pest problem in one season.</p> <p>Do not water turfgrass for at least 12 hours following application of Quillaja Extract. Quillaja Extract is water soluble and does not require additional water application through sprinkler following application.</p>

Application Rates for Control of Fungi

For control/suppression of **POWDERY MILDEW** in the following field and greenhouse-grown crops, apply 1-4 pints Quillaja Extract per acre as a foliar spray in 50-100 gallons

Quillaja Extract; EPA Reg. No. 82572-1
Label changes add directions for use and updated container disposal (PRN2007-4)
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water per acre (equivalent to 0.5-1.5 fl.oz. in 1-2 gallons water per 1,000 sq.ft.) every 7-10 days depending on severity of infection. A surfactant is not necessary, but the addition of a wetting agent, such as Yucca Ag-Aide™, may increase efficacy. Quillaja Extract may be tank mixed with Sterol Inhibitor type fungicides.

Berries and Small Fruits: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Grape (raisin, table, wine), Huckleberry, Kiwifruit, Loganberry, Raspberry (black and red), Strawberry

Bulb Vegetable: Garlic, Leek, Onion (including dry bulb, green and Welch), Shallot

Cereal Grains: Barley, Buckwheat, Corn, Millet, (pearl and proso), Oats, Popcorn, Rice, Rye, Sorghum (milo), Teosinte, Triticale, Wheat, Wild rice

Cole Crops: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables: Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Legume Vegetables (succulent or dried): Bean (*Lupinus*, *Phaseolus* and *Vigna* spp.), Broad bean, Chickpea, Guar, Jackbean, Lablab bean, Lentil, Pea (*Pisum* spp.), Pigeon pea, Soybean, Sword bean

Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)

Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince

Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Gingseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune

Subtropical Fruits: Banana, Date, Mango, Papaya, Pineapple

Additional crops: Hops, Mint (peppermint, spearmint), Tobacco

Herbs and Spices: Allspice, Angelica, Anise, Annatto, Balm, Basil, Borage, Burnet, Camomile, Caper buds, Caraway, Cardamom, Cassia, Catnip, Celery seed, Chervil, Chive, Cinnamon, Clary, Clove buds, Coriander, Coriander,

Costmary, Culantro, Cumin, Curry, Dill, Fennel, Fenugreek, Grains of paradise, Horehound, Hyssop, Juniper berry, Lavender, Lemongrass, Lovage, Mace, Marigold, Marjoram, Mustard, Nasturtium, Nutmeg, Parsley, Pennyroyal, Pepper, Poppy seed, Rosemary, Rue, Saffron, Sage, Savory, Sweet bay, Tansy, Tarragon, Thyme, Vanilla, Wintergreen, Woodruff, Wormwood

Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals

Turf: Ornamental lawns, golf courses and sod farms

For control/suppression of **PHYTOPHTHORA** and **PYTHIUM ROOT ROT** in the following field and greenhouse-grown crops, apply 2-4 quarts Quillaja Extract in 200 gallons water per acre (equivalent to 1.5-3 fl.oz. in 5 gallons water per 1,000 sq.ft.) to achieve a concentration of 2,500-5,000 ppm. Apply in early spring and fall, prior to root flush when soil temperatures are optimum for root infection. Apply to the entire root zone following, or at the end of, an irrigation cycle For best results, repeat application every 7 days, for up to 6 weeks. A surfactant is not necessary, but the addition of a wetting agent, such as Yucca Ag-Aide™, may increase efficacy. Quillaja Extract may be tank mixed with Sterol Inhibitor type fungicides.

Berries and Small Fruits: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Grape (raisin, table, wine), Huckleberry, Kiwifruit, Loganberry, Raspberry (black and red), Strawberry

Citrus: Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo,

Cole Crops: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables: Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)

Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince

Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Gingseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune

Additional crops: Avocado, Kiwifruit

Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals

Application Rates to Enhance Plant Growth and Yield

Under good growing conditions, absent of plant parasitic nematodes or plant parasitic fungi, Quillaja Extract is beneficial to plant growth and yield as described below.

Crop	Benefit	Rate per Acre	Comment
Grapes	Increased Fruit Yield and Root Development	1-2 quarts	Apply at root flush followed by 2-4 applications at 7-14 day intervals.
Citrus	Increased Root Development	1-2 gallons	Apply at root flush followed by 2 quarts/acre every 14 days for 4-6 weeks.
Strawberry	Increased Root Development	2-4 pts	Apply every 14 days for 8-10 weeks.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in cool, dry area.

Pesticide Disposal: Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

Desert King Chile warrants that this product conforms to the chemical description on the label and is reasonable fit for the purposes set forth in the Complete Directions for Use label booklet ("Directions") when used in accordance with those Directions under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Sublabel B: Home Garden and Lawn Use

Quillaja Extract

A Bio-Pesticide

*For Control of Plant Parasitic Nematodes and Plant Parasitic Fungi
in Home Gardens and Lawns*

Active Ingredient:

*Saponins of Quillaja saponaria..... 8.60%

Other Ingredients: 91.40%

Total: 100.00%

*bidesmosidic derivatives of quillajic acid substituted with a trisaccharide at C-3 and an oligosaccharide in C-28

KEEP OUT OF REACH OF CHILDREN

WARNING - ADVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

See back side for additional precautionary statements.

Manufactured for:
Desert King Chile
77 Antonio Bellet, Suite 401
Providencia, Santiago
Chile

EPA Reg. No.: 82572-1
EPA Est. No.: XXXXX-XX-XX

Net Contents: XX Gallons
Batch Code [Lot No.]: XXX

Quillaja Extract; EPA Reg. No. 82572-1

Label changes add directions for use and updated container disposal (PRN2007-4)

MASTER LABEL - Version (12) - November 14, 2011

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye damage. Do not get in eyes or on clothing. Harmful if swallowed or absorbed through skin. Avoid contact with skin. Wear protective eyewear such as goggles, face shield or safety glasses and gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For residential use in home gardens and lawns.

MIXING AND APPLICATION INSTRUCTIONS

Quillaja Extract is a concentrate that is easily mixed with water and applied with band or broadcast type sprayers. After mixing with water, apply solution within three hours of mixing. Irrigate area to be treated before application. After application has been made it may be necessary to water with either drip or above ground sprinklers. Do not over irrigate following application of this product. Over irrigation will move the desired concentration of the product too quickly past the targeted root zone.

If applied in heavy rainfall areas, avoid application during rain or when rain is forecasted within the next 24 hours that may exceed movement of this product past targeted root zone.

Application Rates for Control of Nematodes

Quillaja Extract lessens the damage caused by nematodes and increases yields. To control/suppress plant parasitic nematodes, apply Quillaja Extract to the full irrigated area using the application rate listed.

For around trees, apply from tree trunk to drip-line to cover at least 50% of soil area or the area under the canopy of the tree, whichever is greatest. Single applications should be made in the spring just prior to or during root flush, and again in the fall after harvest.

For best results, multiple applications may be made in the spring every 7 to 14 days for up to 10 weeks, followed by a single application in the fall after harvest.

Use Site	Rate
<p>Berries (Not for use in California): Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Huckleberry, Loganberry, Raspberry (black and red)</p> <p>Citrus: Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo</p> <p>Grapes</p> <p>Nut Trees: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)</p> <p>Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince</p> <p>Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune</p> <p>Cole Vegetables: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizune, Mustard greens, Mustard spinach, Rape greens</p> <p>Cucurbit Vegetables: Chaoyote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, Crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)</p> <p>Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper</p>	<p>Apply 8 fl. oz. of Quijalla Extract in 6 gallons of water per 1,000 sq. ft. Apply every 7-14 days for up to 10 weeks.</p>

(including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables:

Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Strawberry

Bulb Vegetables:

Garlic, Leek, Onion (including dry bulb, green and Welch), Shallot

Root and Tuber Vegetables:

Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Ginseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Ornamentals:

Bare root, container, bedding and flowering plants, landscape, potted flowering, shade and flowering trees, woody ornamentals

Lawns:

For control of *Anguina pacifica* nematode only.

Apply 9 fl. oz. of Quijalla Extract in 3-7 gallons of water per 1,000 sq. ft. using a sprayer with a pressure nozzle tip applicator sufficient to penetrate into the lower part of the turf leaves where *Anguina pacifica* nematode galls are formed. Do not exceed a concentration of 1.5% Quillaja Extract in any application.

Repeat applications every 5-10 days. Additional applications to break the life cycle of the nematode should be repeated 2-4 times within 60 days to significantly reduce this pest problem in one season.

Do not water lawn for at least 12 hours following application of Quillaja Extract.

Quillaja Extract; EPA Reg. No. 82572-1

Label changes add directions for use and updated container disposal (PRN2007-4)

MASTER LABEL - Version (12) - November 14, 2011

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Quillaja Extract is water soluble and does not require additional water application through sprinkler following application.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: To be stored in original container in a cool, well-ventilated areas inaccessible to children and pets. Store above 40°F.

Pesticide/Container Disposal: Nonrefillable container. Do not refill or reuse this container. **If empty:** Place in trash or offer for recycling in available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Desert King Chile warrants that this product conforms to the chemical description on the label and is reasonable fit for the purposes set forth in the Complete Directions for Use label booklet ("Directions") when used in accordance with those Directions under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MECHANABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

[] indicate optional text

Optional Label Claims:

- A Biopesticide
- For Control of Plant Parasitic Nematodes and Plant Parasitic Fungi in Vineyards, Orchards, Field Crops, Turf and Ornamentals (Sublabel A only).
- Controls and/or Suppresses certain foliar diseases such as Powdery Mildew(s)
- Suppresses [Nematodes], [Powdery Mildew]
- For use also on Vegetable Crops Such as: Carrots, Peppers, Tomatoes, Broccoli, Squash, and Beets (Sublabel A only).
- For Control of Plant Parasitic Nematodes and Plant Parasitic Fungi in Home Gardens and Lawns (Sublabel B only).

Quillaja Saponaria, ext.
PC Code: 097095
Product Performance

DP Number: 393379
EPA Reg. No.: 82572-1



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**


10/19/11

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Science Review in Support of the Registration of Quillaja Extract, Containing 8.6 %
Quillaja Saponaria, ext. As Its Active Ingredient.

Decision Number:	452381
DP Number:	393379
EPA File Symbol Number:	82572-1
Chemical Class:	Biochemical
PC Code:	097095
CAS Number:	68990-67-0
Tolerance Exemptions:	40 CFR 180.1278
MRID Numbers:	N/A

FROM: Jacob S Moore, Chemist /s/ 10/19/11 
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: John Fournier, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

In response to deficiencies outlined in a memo from J. Moore to J. Fournier dated 02/08/2011 and sent in a letter to the registrant on 04/29/2011 the registrant has submitted an updated label.

Receipt for Section 3

S: 900374

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 82572 DESERT KING CHILE, LTD.

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 82572-1

Product Name: QULLAJA EXTRACT

Owner:

Me Too

Me Too

Section3:

Product Name:

Application Date: 22-Jul-2011

ie

OPP Rec'd Date: 25-Jul-2011

ie

Front End Date: 25-Jul-2011

ie

Risk Manager Send Date: 27-Jul-2011

ie

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Des

Paper Label

Other

Resp to 4/29/11 letter

< >

View/Edit

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

This is a resp to 4/29/11 defic ltr. See Decis#406151

New Ingredient

Response Date

New Ingredient

Response Date

Form 1

Signature Date

Form 2

Signature Date

Decis#: 452381

C.de 570

Due: 11/12/11

Rec'd
7/26/11
25 AB

APR 29 2011

Amy Plato Roberts, Senior Regulatory Consultant
 Technology Sciences Group, Inc.
 712 Fifth Street, Suite A
 Davis, CA 95616

Subject: Quillaja Extract
 EPA Registration No. 82572-1
 Data Submitted as a Condition of Registration
 Application Dated July 15, 2010
 Decision # 406151

Dear Ms. Roberts:

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the application referred to above, submitted in connection with registration under FIFRA section 3(c)(5). BPPD has concluded that the product performance data submitted in response to the conditions of registration are **not** acceptable, and that the deficiencies listed in the enclosed Confidential Appendix **must** be addressed before we can proceed with the review of your submission and issue the registration for this product.

By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. You will have 75 days from the date of this letter to submit the required information before the Agency will withdraw your application because it is incomplete. If you have any questions please contact John Fournier at 703-308-0169, or by email at fournier.john@epa.gov.

Sincerely,



Linda A. Hollis, Chief,
 Biochemical Pesticides Branch
 Biopesticides and Pollution
 Prevention Division (7511P)

Enclosure		CONCURRENCES					
SYMBOL	7511P	7511P					
SURNAME	Fournier	CPLE					
DATE	9 Mar 11	3/9/11					

~~Confidential Appendix~~

BPPD CONCLUSIONS

Biochemical Pesticides Branch has identified the following deficiencies in the efficacy data:

The studies you submitted do not support the nematicide claims on your product label. You need to establish the relationship between Economic Injury Level (EIL) and damage. Your studies demonstrated that, at the rates applied, the product is not effective against ring nematode under field conditions. While grape yields were increased, they were not statistically significant. Study results seem to indicate that a possible mechanism of induced plant tolerance rather than direct nematicidal effects may be occurring upon repeated application of the product. The exact mechanism for plant protection, increased yields, or decreased nematode activity is unknown. In conclusion, your results are highly variable depending on the nematode species, crop, and perhaps crop variety. You should measure the efficacy of the product against the EIL of each crop used as the efficacy standard. Otherwise, the product label must indicate what the product does and recommend that it be used in combination with other products to achieve economically meaningful control of the target pest.

MATERIAL TO BE ADDED TO JACKET

REG #: 82572-1

Description: correspondence

if applicable, check all that are attached:		Send to CSC
<input type="checkbox"/>	new stamped accepted label	
<input type="checkbox"/>	new CSF	
<input type="checkbox"/>	notification	
<input checked="" type="checkbox"/>	other: response to conditional data submission	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer: John Fournier Date: 5/4/2011

Phone: (703) 308-0169 Division: BPPD

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 29 2011

Amy Plato Roberts, Senior Regulatory Consultant
Technology Sciences Group, Inc.
712 Fifth Street, Suite A
Davis, CA 95616

Subject: Quillaja Extract
EPA Registration No. 82572-1
Data Submitted as a Condition of Registration
Application Dated July 15, 2010
Decision # 406151

Dear Ms. Roberts:

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the application referred to above, submitted in connection with registration under FIFRA section 3(c)(5). BPPD has concluded that the product performance data submitted in response to the conditions of registration are **not** acceptable, and that the deficiencies listed in the enclosed Confidential Appendix **must** be addressed before we can proceed with the review of your submission and issue the registration for this product.

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Sincerely,



Linda A. Hollis, Chief,
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

		CONCURRENCES					
SYMBOL	7511P	7511P					
SURNAME	Fournier	COLE					
DATE	9 Mar 11	3/9/11					

~~Confidential Appendix~~

BPPD CONCLUSIONS

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

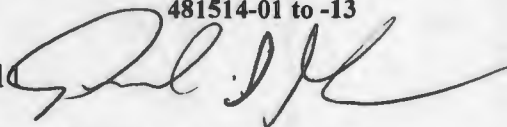
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

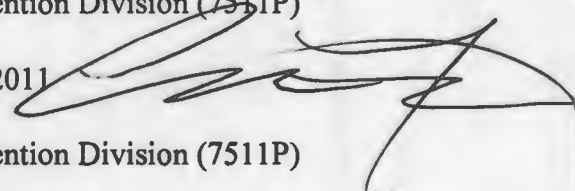
MEMORANDUM

DATE: February 7, 2011

SUBJECT: Science Review in Support of the Registration of Quillaja Extract, Containing 8.6% Quillaja Saponaria, ext. as its Active Ingredient.

Decision Number:	406151
DP Number:	380597
EPA File Symbol Number:	82572-1
Chemical Class:	Biochemical
PC Codes:	097095
CAS Number:	68990-67-0
Active Ingredient Tolerance Exemptions:	40 CFR §180.1278
MRID Numbers:	481514-01 to -13

FROM: Jacob Moore, Chemist /s/ 02/07/2011 
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THROUGH : Clara Fuentes, Ph.D. /s/ 02/08/2011 
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: John Fournier, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

Driss Benmhend, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

Desert King Chile, Ltd. requests registration of Quillaja Extract. This product is intended for use as a nematicide on various crops, including, but not limited to, grapes, oranges, russet potatoes,

Quillaja Saponaria
PC Code: 097095

DP Number: 380597
EPA Reg. No.: 82572-1

and cucumbers. In support of this registration, the registrant has submitted product performance data in MRIDs 481514-02 to -13.

RECOMMENDATIONS AND CONCLUSIONS

1. Product Performance data is **UNACCEPTABLE**. See **product performance summary below for more information**. The studies presented by the registrant do not support label claims. The registrant needs to establish the relationship between Economic Injury Level (EIL) and damage. At the rates applied, the product is not effective against ring nematode under field conditions. While grape yields were increased they were not statistically significant. Study results seem to indicate that a possible mechanism of induced plant tolerance rather than direct nematicidal effects may be occurring upon repeated application of the product. The exact mechanism for increased product yields or decreased nematode activity is unknown. In conclusion, results are highly variable, depending on nematode spp., crop and maybe crop variety although that has not been tested. Possible mechanisms of plant protection are unknown. The registrant should measure the efficacy of its product against the EIL of each crop used as the efficacy standard. Otherwise, the label should indicate what the product does and recommend that it be used in combination with other products to achieve economically meaningful control of the pest.

Product Performance (No DERs were created for these studies)

MRID 481514-02:

This study was conducted to evaluate the effect of Quillaja Extract on nematodes in Chardonnay Grape. The effect of two repeated applications of the product on ring nematodes populations were compared to an untreated control. A damage level of 60 ring nematodes / 250 g soil is set in vineyards. Damage is not the same as Economic Injury Level (EIL). Damage could be sustained without economic loss. The relationship between damage and EIL has not been established, and it should be based on the results presented in this study, Quillaja Extract (applied at a rate of 3 gal/Acre or 1.5 /A at 8 weeks interval) is not effective against ring nematode, *Mesocriconema xenoplax*, under field conditions.

MRID -03:

This study was conducted to compare the effects of two nematicides on nematodes and yield of Chardonnay Grapes. Quillaja Extract was compared to DiTera and an untreated control. No statistically significant reduction in number of ring nematodes, *M. xenoplax*, due to treatments. Application rates were 2.5 gal/A at 8 weeks intervals. Grape yields were numerically increased but not to a statistically significant amount. This may be due to increased root growth or plant tolerance but this has not been tested.

MIRD -04:

This study was conducted to compare the effects of Quillaja Extract, Nemacur 3 EC and DiTera DF for control of Northern root-knot nematode on Chardonnay Grape. Repeated applications of Quillaja Extract (5 applications of 1 qt/A at 2 weeks intervals) significantly reduced lesion and ring nematodes. The treatments also enhanced plant growth.

MRID -05:

This study was conducted to compare the effects of Quillaja Extract, Nemacur 3 EC and DiTera DF for control of Northern root-knot nematode on Chardonnay Grape at the same rate of applications as MRID 481514-04. Results continue to indicate that a possible mechanism of induced plant tolerance rather than direct nematicidal effects may be occurring.

MRID -06:

This study was conducted to evaluate the effects of Quillaja Extract as compared to other nematicides on Russet Burbank potato. The study shows no correlation between nematode numbers and damage. Nematode numbers were not reduced. Significantly improved potato yields could have resulted from reduced nematode feeding but not numbers at early stages of potato growth when the plant is most susceptible. The exact mechanism is unknown.

MRID -07:

This study was conducted to compare the effects of Quillaja Extract on Valencia oranges to an untreated control and another nematicide. No significant differences were found between treatments on Valencia oranges.

MRID -08:

This study was conducted to investigate the effects of Quillaja Extract on Valencia oranges. Infestations of citrus roots by female citrus nematodes was reduced however, larvae population increased slightly. Possible explanations are that treatments may have prevented the larvae from entering the roots or it may have arrested their development inside the roots. Exact mechanism is unknown.

MRID -09:

This study was conducted to compare the effects of single and multiple applications of Quillaja Extract on Valencia oranges. Repeated applications were more effective than one time application in reducing population build up of females and larvae over the entire experimental period.

MRID -10:

As in MRID 481514-10, this study was conducted to compare the effects of single and multiple applications of Quillaja Extract on Valencia oranges. However, there was too much variability in the results of this study. The repeated treatment shows a significant difference in increase of females between third and 4th treatment and control.

Quillaja Saponaria
PC Code: 097095

DP Number: 380597
EPA Reg. No.: 82572-1

MRID -11:

This study was conducted to compare the efficacy of three nematicides in Grape cv. Flame crops. Treatments of Quillaja Extract were effective against plant parasitic nematodes, root-knot nematode, ring nematodes and lesion nematodes.

MRID -12:

This study was conducted to compare the efficacy of three nematicides in Table Grape crops. There was significant effect on dagger (80% reduction) and root-knot nematode (90% reduction).

MRID -13:

This study was conducted to evaluate the efficacy of Quillaja Extract at two rates to control the Root knot nematode in cucumber crops. Root knot nematode numbers were significantly lowered at the end of the experiment due to Quillaja Extract treatment.

cc: J. Moore, C. Fuentes, J. Fournier, D. Benmhend, BPPD Science Review File, IHAD/ARS
J. Moore, C. Fuentes FT, PY-S: 02/07/2011.

**WASHINGTON**

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Linda Hollis

John Fournier

Biopesticide and Pollution Prevention Division

Office of Pesticide Programs

Environmental Protection Agency

Room S-4900, One Potomac Yard

2777 South Crystal Drive

Arlington, VA 22202-4501

July 15, 2010

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

RE: Quillaja Extract (EPA Reg. No. 82572-1)**Response to EPA letter dated October 28, 2009**

Dear Ms. Hollis and Mr. Fournier:

Technology Sciences Group, on behalf of Desert King Chile, is submitting the response to the above referenced letter.

EPA Comment No. 1a.

The tested products are not properly identified as requested by OPPTS Guideline 810.1000. The registered name of the tested product is Quillaja Extract, but the unregistered names QLAGri, and QLAGri35 are used in the studies together with the distributor's name Nema-Q. The trademarks EF500 and NemaCure are also used in comparative tests. You must use the currently registered name in all studies or submit an application to amend your registration to include QLAGri, QLAGri 35, and Nema-Q on the product label as alternative brand names of EPA Reg. No. 82572-1. You must also provide additional information identifying EF500 and NemaCure, including their EPA registration numbers and producers.

Desert King Response

Desert King has submitted a notification (dated July 13, 2010) to add the alternate brand names to the label with the exception of Nema-Q. Nema-Q is a supplemental distributor brand name and the EPA Form 8570-5 is being

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

submitted in lieu of a notification. The EF500 is now sold as Soil Shot®, a 25(b) exempt product sold by USAgritech, Inc. Nematicur, appears to be a cancelled and/or transferred product but was previously sold by Bayer Agrochemicals. Volume 2 discusses this further and provides product labeling.

EPA Comment No. 1b.

There is a discrepancy between the percentage of the active ingredient in the most current CSF (7.5%) and the ingredient statement on the label (8.6%). You must submit an application to amend your CSF to include the correct percentage of active ingredient.

Desert King Response

According to our records, the most recent CSF dated January 22, 2009 was approved on February 2, 2009 by John Fournier. This was submitted with an amendment to change the manufacturing process to reduce the amount of impurities thus reducing the eye irritation of Quillaja Extract. This approved CSF has the active ingredient listed at 8.6%, which is consistent with the label. A copy is included in this response.

EPA Comment No. 1c.

The comparison between the effects of Quillaja Extract and the other trademark nematicides is often omitted in the conclusions.

Desert King Response

Please see the enclosed efficacy discussion data volume 2 for this discussion.

EPA Comment No. 1d.

The product CropGuard (EPA Reg. No. 7655-1), containing 85% Silicon Dioxide from Diatomaceous Earth, is used in some studies as a positive control but is not a registered nematicide.

Desert King Response

The CropGuard used in the trials is not the same product that is registered with as EPA Reg. No. 7655-1) but is another product. Please go to <http://www.cropguard.co.za/home.html> for

information on this product. A label is also submitted in Volume 2 herein.

EPA Comment No. 1e.

Please prepare a brief summary explaining which label claims for Quillaja Extract are supported by the results of the submitted efficacy studies.

Desert King Response

Please see the enclosed efficacy discussion data volume 2 for this discussion.

EPA Comment No. 1f.

The statistical differences are reported and graphed based on transformed values, $\log_{10}(x+1)$. Graphs should be constructed using the original values to better illustrate study results.

Desert King Response

The enclosed efficacy studies include graphs constructed with the original values.

EPA Comment No. 1g.

In order for the product to be effectively used for maintaining manageable pest population levels when used in IPM programs, it is important to assess whether this product is effective in keeping the pest population below economic injury levels, established from 12,000 to 18,000 larvae per 500 cc soil or 1,100 to 1,400 females per gram of root.

Desert King Response

The trials submitted previously as well as the trials submitted with this response provide the larvae and female counts at treatment time and for certain periods post treatment. In most of the trials, Quillaja Extract kept the larvae and female numbers below the economic injury levels.

EPA Comment No. 1h.

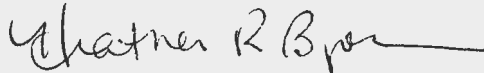
For practical agricultural purposes, it is important to assess the relationship between product performance on the pest and its indirect effect of yield enhancement.

Desert King Response

The early trials conducted in 2004 (MRID Nos. 46972504 – 46972510) submitted to the Agency have information on Quillaja Extract's effect on increasing the yield of crops. Walnut and grape studies (MRID Nos. 46972506, 46972509 respectively) also have data on yield. The efficacy discussion in Volume 2 discusses this issue further.

Please do not hesitate to contact me directly with any questions and/or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Heather R. Bjornson", with a long horizontal flourish extending to the right.

Heather R. Bjornson

Regulatory Agent for Desert King Chile/Desert King International

VOLUME 1 OF 14 SUBMISSION

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Desert King Chile, Ltd.
Antonio Bellet 77 Of. 401
Providencia, Santiago, Chile

REGULATORY ACTION:

Submission of efficacy data to support Quillaja Extract (EPA Reg. No. 82572-1) in response to Agency letter dated October 28, 2009.

TRANSMITTAL DATE:

July 15, 2010

LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
	1 of 14	(Transmittal Document)	-----
48151401	2 of 14	Discussion on Efficacy Trials on Quillaja Extract	810.2700
48151402	3 of 14	Efficacy of <i>Quillaja Extract</i> on Chardonnay Grapes – Trial Two	810.2700
48151403	4 of 14	Efficacy of <i>Quillaja Extract</i> on Chardonnay Grapes – Trial Three	810.2700
48151404	5 of 14	Efficacy of <i>Quillaja Extract</i> on Chardonnay Grapes – Trial Four	810.2700
48151405	6 of 14	Efficacy of <i>Quillaja Extract</i> on Chardonnay Grapes – Trial Five	810.2700
48151406	7 of 14	Efficacy of <i>Quillaja Extract</i> on Russet Burbank Potato	810.2700
48151407	8 of 14	Efficacy of <i>Quillaja Extract</i> on Valencia Orange – Trial One	810.2700

48151408	9 of 14	Efficacy of <i>Quillaja Extract</i> on Valencia Orange – Trial Two	810.2700
48151409	10 of 14	Efficacy of <i>Quillaja Extract</i> on Valencia Orange – Trial Three	810.2700
48151410	11 of 14	Efficacy of <i>Quillaja Extract</i> on Valencia Orange – Trial Four	810.2700
48151411	12 of 14	Efficacy of <i>Quillaja Extract</i> on Grapes cv. Flame	810.2700
48151412	13 of 14	Efficacy of <i>Quillaja Extract</i> on Table Grapes	810.2700
48151413	14 of 14	Efficacy of <i>Quillaja Extract</i> on Cucumber	810.2700

COMPANY NAME: Desert King Chile, Ltd.

COMPANY OFFICIAL:



Heather R. Bjornson, Regulatory Agent

COMPANY CONTACT:

Heather R. Bjornson, Regulatory Agent
Technology Sciences Group, Inc.
1150 18th Street, N.W. Ste. 1000
Washington, DC 20036
(202) 828-8945



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82572-1	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Quillaja Extract	PM# BPPD/Biochemical Pesticides	
5. Name and Address of Applicant (Include ZIP Code) Desert King Chile, Ltd. Antoinio Bellet 77 Of 401 Providencia, Santiago, Chile <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>10-28-2010</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input checked="" type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 5 gal pale; 30 & 55 g drum; 270g tote		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Heather R. Bjornson, Technology Sciences Group, Inc.		Title Regulatory Consultant	
		Telephone No. (Include Area Code) (202) 828-8945	
<p align="center">Certification</p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>			
2. Signature 		3. Title Regulatory Consultant to Desert King Chile	
4. Typed Name Heather R. Bjornson		5. Date July 15, 2010	
6. Date Application Received (Stamped)			



1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

FEB 15 2011

Date: February 10, 2011
OPP Decision Number: 438575
EPA File Symbol or Registration Number: 82572-1
Product Name: Quillaja Extract
EPA Receipt Date: August 12, 2010
EPA Company Number: 82572
Company Name: Desert King Chile, Ltd.

Registrant Contact: Technology Sciences Group, Inc.
Registrant Name: Desert King Chile, Ltd.
Registrant Address: C/O Technology Sciences Group, Inc.
1101, 17th Street, N.W., Suite 500
Washington, DC 20036

Subject: Confirmation of Request to Withdraw an Application

Dear Ms. Roberts:

This is to confirm that the Agency has received and processed your request of February 10, 2011, to withdraw the above referenced application. BPPD has fully reviewed this application; therefore we have determined that no refund is owed on this action. In the event that a new application for registration related to this action is submitted in the future, it must be submitted as a new application requiring either the entire PRIA fee, or payment of 25 percent or 50 percent, accompanied by valid justification as to why the remaining 75 percent or 50 percent, respectively, should be waived.

If you have questions concerning this letter, Please contact the regulatory action leader, Mr. Driss Benmhend, at (703) 308-9525 or via email at benmhend.driss@epa.gov.

Sincerely,

Keith A. Matthews, Director
Biopesticides and Pollution
Prevention Division (7511P)

BPPD WITHDRAW FORM

Name of person requesting withdrawal (Branch Chief, RAL, etc.)

Requestor: Driss Benmhend

Date: 2/16/11

Reg./File Symbol: 82572-1

Decision #: 438575

Submission #: 880334

Data Package # N/A

1. DOCUMENTATION:

Registrant letter requesting withdrawal filed in jacket? Yes ☒ No ☐

Agency initiated withdraw letter to Registrant filed in jacket? Yes ☐ No ☐

If no, explain:

2. PRIA Action: Yes ☒ No ☐ (if no, explain below then precede to #3 below)

Was a Fee-For-Service (FFS) paid to EPA? No ☐ Yes ☒

If yes, how much? \$5,513.00

Refund due to Registrant? Yes ☐ (justification for refund) No ☒

Comment:

BPPD has fully reviewed this application; therefore we have determined that no refund is owed on this action.

Percentage of work completed (see your Team Leader/Branch Chief for assistance)? 100%

3. OPPIN:

Response Code: 1350 Withdrawn: Yes ☒ No ☐ (if OPPIN issue, explain, then forward to OPPIN Manager)

Withdrawn in OPPIN By: John Jamula

Date 2/16/11

4. MITS:

Date Reported _____ SCR #: _____ Date Complete: _____

Withdrawn in OPPIN By: John Jamula

Date

5. REFUND: (To be completed by OPPIN Manager)

Amount: \$ _____ Notice sent to ITRMD/ISB? Yes ☐ No ☐

Sent by:

Date:

Copy to Jacket

Copy to OPPIN Manager

3/6/2007

Technology Sciences Group Inc.

712 Fifth St., Suite A
Davis, CA 95616
Direct in CA: (530) 757-1432
Direct in DC: (202) 828-8964
Fax: (530) 757-1299
E-Mail: aroberts@tsgusa.com

Amy Plato Roberts
Senior Regulatory Consultant



Linda Hollis, Chief, Biochemical Pesticides Branch
Driss Benmhend, RAL, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs, EPA
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

February 10, 2011

**RE: Quillaja Extract (EPA Reg. No. 82572-1)
PRIA B650 Label Amendment submitted 8-24-10**

Request for Withdrawal

Dear Ms. Hollis and Mr. Benmhend:

With this letter we hereby request the withdrawal of the pending B650 label amendment for the above referenced product.

Per our recent communication, our understanding is the Agency will not allow a new use pattern (residential use) for nematode pests due to the fact that the Agency's review of conditionally-required efficacy data on nematodes has been found to be insufficient. Until such a time the nematode efficacy data deficiencies are resolved, further expansion of this product label for this pest will not be allowed. **At the Agency's specific request, we are thus withdrawing this amendment.**

We look forward to receipt of the Agency's DER on the conditionally-required efficacy data and the next steps to resolve this issue. Please do not hesitate to let me know if you have any questions or comments.

Sincerely,

Amy Plato Roberts
Regulatory Consultant for Desert King Chile
Direct dial: (530) 757-1432; E-mail: aroberts@tsgusa.com

Washington, D.C.

1150 18th St., NW, Suite 1000
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Phone: (202) 223-4392

California

712 Fifth St., Suite A
Davis, CA 95616
Phone: (530) 757-1245

Canada

275 Slater St., Suite 900
Ottawa, Ontario K1P 5H9
Phone: (613) 247-6285

Receipt for Section 3

S: 860334

Regulatory Type: **Product Registration - Section 3** Fee For Service: ☐ Yes ☒ No

Application Type: **Amendment** Billable: ☒ Yes ☐ No

Company: 82572 **DESERT KING CHILE, LTD.** **V**

Risk Manager: **Biologicals & Pollution Prevention Division, PM Team 91**

Product #: 82572-1 Product Name: **GUILLAJA EXTRACT**

Me Too Section3: Me Too Product Name:

Application Date: 12-Aug-2010 **ic** OPP Rec'd Date: 13-Aug-2010 **ic**

Front End Date: 13-Aug-2010 **ic** Risk Manager Send Date: **ic**

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Description: **Label amendment; new use**

View/Edit

Form A Signature Date: Form B Signature Date:

Decis # 438575 Code: B650, 6 months 1st Res use for a:

FFS Start Date: 9/3/10 PRIA Due Date: 3/3/2011

Phase I: 10/18/10

Phase II: N/A

Phase III: 11/18/10

Phase IV: 1/18/2011

Phase V: 3/3/2011

This is 1st resid. use For the a.v. This action fall under Public Participation
The planned comment start date is 1/20/10

Checklist to determine if a product is subject to 30 day comment period:

Product: Quillaja Extract

EPA File symbol: 82572-1

Submission Number: S880334

Active Ingredient (s): quillaja extract

		Yes	No
1.	Is it a new active ingredient?		X
2.	Is it a first food use?		X
3.	Is it a first outdoor use?		X
4.	Is it first residential use?	X	
a.	- does label indicate the product is for homeowner/residential use (Refer to 40 CFR 152.3 Definitions. <i>Residential use</i> means use of a pesticide directly: (1) On humans or pets, (2) In, on, or around any structure, vehicle, article, surface, or area associated with the household, including but not limited to areas such as non-agricultural outbuildings, non-commercial greenhouses, pleasure boats and recreational vehicles, or (3) In any preschool or day care facility.		
b.	-Does the label storage and disposal statement indicate for homeowner use. LRM Ch13, VI, A for example		
c.	- Does the label have the Agricultural Use Requirements Box		
d.	- If the label does have the Agricultural Use Requirements Box does it also have the Non- Agricultural Use Requirements Box		
e.	- Check container sizes. Are they small? For example in ounces.		
f.	-Check application rate. For example are all of the instructions in XXX per acre.		
5.	RAL - Indicate the date of posting the Federal Register Notice publication (1st) on the Agency's web site.		

This action does fall under the 30 day public comment period. This action is a first residential use.

BPPD Label Amendment Checklist

Fast Track ☐ and PRA Actions B650 ☐, B680 ☐, B681 ☐, B730 ☐, B890 ☐ & B900 ☐

EPA Reg. No.:

RAL:

Application Date:

#	Check list Item	Yes	No
1.	Application Form (EPA Form 8570-1) - signed & complete, including package type? IF NO, STOP! Call applicant and have them correct application and resubmit.		
2.	Final printed labeling received for previous action? IF NO, STOP! E-mail applicant and request final printed labeling (FPL).		
3.	Does the registration notice have terms/conditions (ex: storage stability data)? If so have the terms/conditions been met?		
4.	If new use sites are being added, are they subject to OPP's process for public involvement in pesticide registration actions?		
5.	Data and Data Matrix present. (EPA Form 8570-35) NA <input type="checkbox"/> If Fast Track, check to see if original registration supported by data, formulators exemption, etc.		
a.	Using Selective Method? [IF NO, SKIP to item 4 and note that data matrix should be used for the cite-all method to indicate the companies to whom offers of compensation were made.]		
b.	Complete Data Matrix supporting both the product registration and the proposed amendment. Minimum Data Matrix for registration includes: Product specific Acute Toxicity and Product Chemistry data, plus Efficacy data for public health pests claimed on label.		
c.	Adequate product specific data?		
d.	Registered source used for active ingredient? IF YES, SKIP to ITEM 4. (If active ingredient is from a registered source (manufacturing-use product), generic data should be satisfied by registered source.) IF NO or if use not supported by registered source, generic data is necessary.		
e.	If new data submitted: data passed PR Notice 86-5 for formatting and MRID # assigned?		
f.	Public copy of Data Matrix provided? (PRN 98-5)		
6.	Certification with Respect to Citation of Data present. (EPA Form 8570-34): See 40 CFR 152.80-98 and PR Notice 98-5 [If no data are required or submitted, a Certification with Respect to Citation of Data form isn't needed. This is often true for minor amendments.] NA <input type="checkbox"/>		
a.	Did applicant check a Method of Support?		
b.	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?		
c.	Is the form signed and dated?		
d.	Check form and Data Matrix. Are Exclusive Use data cited from other sources? IF YES, is the required authorization letter included in application? NA <input type="checkbox"/>		
7.	Label(s) Review <u>Date of Label Review:</u>		
a.	Label(s) in conformance with current <i>Label Review Manual</i> and appropriate REDS.		
b.	Labeling statements and claims are supported by Acute Toxicity, Product Chemistry data (or acceptable waivers). Acceptable efficacy studies support public health pests claimed on label.		
c.	Nominal concentration of active ingredient shown in ingredients statement.		
d.	Viability included as sub-statement of Ingredient Statement (if live microbial, i.e., cfu/gram).		
e.	Storage and disposal instructions agree with container types listed on application form.		
f.	Unique Product Name for Same Company (Check OPPIN).		
g.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? If YES, RAL must evaluate label use directions for compliance with 40 CFR 180.1071.		

h.	Does label bear "National Organic Program" (PR Notice 2003-1) or OMRI claims?		
	If YES, National Organic Program or OMRI claims approved by Chris Pfeifer?	NA <input type="checkbox"/>	
i.	Labeling is acceptable. Corrections or changes are NOT necessary.		
j.	Comments:		

Internal BPPD Guidance Document – Other Items May be Required

Label Review

File Symbol: _____ Date: ____/____/____ Reviewer: _____

[Site/Use]	[Res /Ag /Both] [Food /Non-Food /Both]				
[Tox Categories:]	[AcOral: /AcDerm: /AcInhl: /EyeIrr: /SkinIrr: DermSens:]				
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
Restricted Use Pesticide	-----	-----	----		Ch 6
Product Name					Pg 12-3
Compny Name and Info					Pg 15-1
Identification Numbers					Ch 14
Net Contents					Ch 17
Ingredients Statement					Ch 5
Label Claims					Pgs 4-5, 5-7 11-10 & Ch 12
Alternate Formula					5-12

Precautionary Statements					
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
KOROC					3-1 & 9 7-3 & 4
Signal Word					Ch 3 Ch 7 Ch 10
General Heading >PRECAUTIONARY STATEMENTS=					Ch 7
First Aid (PRN 20001-1)					Ch 3 & 7

Hazards to Humans and Domestic Animals					Ch 3, 7-3
PPE (WPS) Engineering Controls					Ch 7, Pg 7-12 Pgs 10-4, 15
User Safety Requirements					Ch 10
User Safety Recommendations					Ch 10
Environmental Hazards					Ch 8
Physical and Chemical Hazards					Pg 3-4 Ch 9

Directions for USE (FIFRA Text, WPS plus Storage and Disposal)					
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
Header >Directions for Use=					10-16
Violation of Federal Law text					10-26, 11-7
WPS Text (PPE)					Ch 10, 7-1 7-11
Non-WPS Text					7-12, Ch 10
Pesticide Storage and Disposal					11-16, Ch 13
Container Disposal & Batch Code					PRN 2007-4

Directions for Use (General Instructions and Information)					
Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
General Instructions and Sub-Header					
Chemigation / Prohibition					PRN
REI					Pg 10-20

Label Requirement	Acceptable	Not Acceptable	N/A	Comments Recommendations	LRM3
General Info. (non-site specific info. on uses, pests, mixing, and loading, tank mixing, etc.)					
General Precautions and Restrictions					
Directions for Use					
Directions for Application					
Warranty Information					
Consistency with label instructions					12-6
Not false or misleading					
<p>"The warranty section contains an overly broad statement concerning limitations of liability. As such, this statement may be misleading and may constitute misbranding under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It is suggested that the existing statement be preceded by the phrase, to the extent allowable by state law, or otherwise qualified to make it clear that this warranty is not intended to be a statement of law which implies that the buyer has no legal rights to recover damages from the manufacturer if he/she suffered a loss or injury from the product and concludes that it would be futile to pursue what might in reality be a valid claim."</p>					



WASHINGTON

1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Linda Hollis
Chief, Biopesticide and Pollution Prevention Division
Office of Pesticide Programs
Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

August 12, 2010

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

RE: Quillaja Extract (EPA Reg. No. 82572-1)

PRIA Category B650: Label amendment; new use

Dear Ms. Hollis:

Technology Sciences Group, on behalf of Desert King Chile, is submitting the enclosed label amendment to make a master label and add a Home and Garden sublabel. You will find the following in support of this amendment:

- 1) Amendment application form,
- 2) One redline version of the label,
- 3) Three clean copies of the revised label,
- 4) Small business waiver and supporting documentation, and
- 5) PRIA pre-payment receipt: pay.gov tracking ID: 251HS7G; Agency tracking ID: 74131763441.

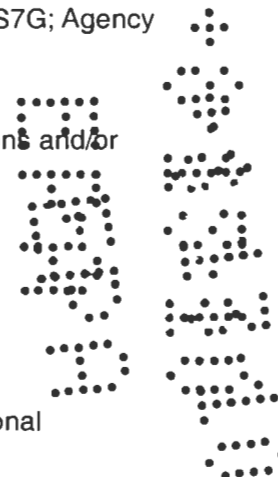
CANADA

275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

Please do not hesitate to contact me directly with any questions and/or concerns.

Sincerely,

Heather R. Bjornson
Regulatory Agent for Desert King Chile/Desert King International





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82572-1	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Quillaja Extract	PM# BPPD/Biochemical Pesticides	
5. Name and Address of Applicant (Include ZIP Code) Desert King Chile, Ltd. Antoinio Bellet 77 Of 401 Providencia, Santiago, Chile <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

PRIA Category B650: Amendment with New Use. Please confirm via e-mail: hbjornson@tsgusa.com

PRIA pre-payment receipt: Pay.gov tracking ID: 2519HS7G; Agency tracking ID: 74131763441.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted				Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 5 gal pale; 30 & 55 g drum; 270g tote	5. Location of Label Directions <input checked="" type="checkbox"/>			
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather R. Bjornson, Technology Sciences Group, Inc.	Title Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8945
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant to Desert King Chile	
4. Typed Name Heather R. Bjornson	5. Date August 12, 2010	

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 2519HS7G

Agency Tracking ID: 74131763441

Transaction Date and Time: 08/12/2010 18:36 EDT

Payment Summary

Address Information

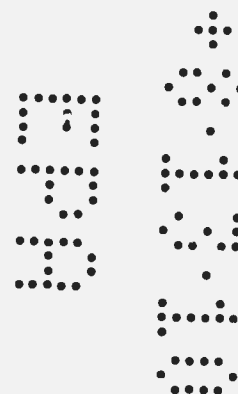
Account Holder Heather R
Name: Bjornson
1150 18th Street
Billing Address: NW
Billing Address
2: Ste. 1000
City: Washington
State / Province: DC
Zip / Postal
Code: 20036
Country: USA

Account Information

Card Type: American Express
Card Number: *****1436
Decision
Number:
Registration
Number: 82572-1
Company Desert King
Name: International
Company
Number: 82572
Action Code: B650

Payment Information

Payment Amount: \$1,378.25
Transaction Date 08/12/2010
and Time: 18:36 EDT





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OCT 28 2009

Heather R. Bjornson, Regulatory Agent
Technology Sciences Group, Inc.
1150 18th Street, N.W. Ste. 1000
Washington, DC 20036

Subject: Quillaja Extract
EPA Registration No. 82572-1
Data Submitted as a Condition of Registration
Application Dated January 15, 2009
Decision # 406151

Dear Ms. Bjornson:

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the application referred to above, submitted in connection with registration under FIFRA section 3(c)(5). BPPD has concluded that the efficacy data submitted in response to the conditions of registration are not acceptable, and that the following deficiencies must be addressed before we can proceed with the review of your submission and issue the registration for this product.

BPPD CONCLUSIONS

1. Biochemical Pesticides Branch has identified the following deficiencies in the efficacy data:
 - a. The tested products are not properly identified as requested by OPPTS Guideline 810.1000. The registered name of the tested product is Quillaja Extract, but the unregistered names QLAGri, and QLAGri35 are used in the studies together with the distributor's name Nema-Q. The trademarks EF500 and Nema-cur are also used in comparative tests. You must use the currently registered name in all the studies or submit an application to amend your registration to include QLAGri, QLAGri35, and Nema-Q on the product label as alternative brand names of EPA Reg. No. 82572-1. You must also provide additional information identifying EF500 and Nema-cur, including their EPA registration numbers and producers.

- b. There is a discrepancy between the percentage of the active ingredient in the most current CSF (7.5%) and the ingredient statement on the label (8.6%). You must submit an application to amend your CSF to include the correct percentage of active ingredient.
- c. The comparison between the effects of Quillaja Extract and the other trademark nematicides is often omitted in the conclusions.
- d. The product CropGuard (EPA Reg. No. 7655-1), containing 85% Silicon Dioxide from Diatomaceous Earth, is used in some studies as a positive control but is not registered as a nematicide.
- e. Please prepare a brief summary explaining which label claims for Quillaja Extract are supported by the results of the submitted efficacy studies.
- f. The statistical differences are reported and graphed based on transformed values, $\log_{10}(x+1)$. Graphs should be constructed using the original values to better illustrate study results.
- g. In order for the product to be effectively used for maintaining manageable pest population levels when used in IPM programs, it is important to assess whether this product is effective in keeping the pest population below economic injury levels, established from 12,000 to 18,000 larvae per 500 cc soil or 1,100 to 1,400 females per gram of root.
- h. For practical agricultural purposes, it is important to assess the relationship between product performance on the pest and its indirect effect on yield enhancement.

By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. You will have 75 days from the date of this letter to submit the required information before the Agency will withdraw your application because it is incomplete. If you have any questions please contact John Fournier at 703-308-0169, or by email at fournier.john@epa.gov.

Sincerely,



Linda A. Hollis, Chief,
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Efficacy testing against nematodes.

MRID 481514-02:

A damage level of 60 ring nematodes / 250 g soil is set in vineyards. (Reviewer comment: Damage is not the same as Economic Injury Level (EIL). Damage could be sustained without economic loss. The relationship between damage and EIL has not been established, and it should be.)

Based on the results presented in this study, Quillaja Extract (applied at a rate of 3 gal/Acre or 1.5 /A at 8 weeks interval) is not effective against ring nematode, *Mesocriconema xenoplax*, under field conditions.

MRID -03:

No statistically significant reduction in number of ring nematodes, *M. xenoplax*, due to treatments. Application rates were 2.5 gal/A at 8 weeks intervals. Grape yields were numerically increased, but not statistically significant. This was maybe due to increased root growth or plant tolerance which has not been tested.

MIRD -04:

Repeated applications of Quillaja Extract (5 applications of 1 qt/A at 2 weeks intervals) significantly reduced lesion and ring nematodes. The treatments also enhanced plant growth.

MRID -05:

Same rate of applications as above. Results continue to indicate that a possible mechanism of induced plant tolerance rather than direct nematicidal effects may be occurring.

MRID -06:

The study shows no correlation between nematode numbers and damage. Nematode numbers were not reduced. Significantly improved potato yields could have resulted from reduced nematode feeding but not numbers at early stages of potato growth when the plant is most susceptible. The exact mechanism is unknown.

MRID -07:

No significant differences between treatments on Valencia oranges.

MRID -08:

Infestations of citrus roots by female citrus nematodes was reduced however, larvae population increased slightly. Possible explanations are that treatments may have prevented the larvae from entering the roots or it may have arrested their development inside the roots. Exact mechanism is unknown.

MRID -09:

Repeated applications were more effective than one time application in reducing population build up of females and larvae over the entire experimental period.

MRID -10:

There was too much variability. The repeated treatment shows a significant difference in increase of females between third and 4th treatment and control.

MRID 11:

Treatments were effective against plant parasitic nematodes, root-knot nematode, ring nematodes and lesion nematodes.

MRID 12:

There was significant effect on dagger (80% reduction) and root-knot nematode (90% reduction).

MRID -13:

Root-knot nematode numbers were significantly lowered at the end of the experiment due to Quillaja Extract treatment.

In conclusion, results are highly variable, depending on nematode spp., crop and maybe crop variety although that has not been tested. Possible mechanisms of plant protection are unknown. Induced plant tolerance has been suggested but not demonstrated. On page 4 of MRID 481514-01, registrant claims that there are no efficacy standards while Economic Injury Level (EIL) is set at 12,000 to 18,000 larvae/ 500 cc soil, or 1,100 to 1,400 females / g soil. The EIL should be treated as the efficacy standard.

The EIL is usually a function of crop and crop variety within crop as well as nematode spp. and other variables (i.e., pest biology such as developmental stage or gender). It will be useful to know the EIL for each crop. The relationship between crop type, pest population level, amount of damage and EIL has not been established, and it should be. A resistant or tolerant variety, for example, is able to withstand the same or even more damage than a more susceptible variety below its EIL. Thus, the EIL of a tolerant variety is set at a higher pest pressure and more damage than a susceptible one. In summary, it is unknown how much pest suppression is needed to keep damage below EIL for each crop. For practical purposes, the EIL for each crop should be used as the efficacy standard because just some level of reduction in pest population may not have meaningful economic implications.

There has to be information on EIL for different crops in the public literature. We should request that the registrant measures the efficacy of its product against the EIL of each crop used as the efficacy standard. Otherwise, the label should indicate what the product does and recommend that it be used in combination with other products or methods to achieve economically meaningful control of the pest.

Master Label:
Sublabel A: Agricultural and Commercial Use
Sublabel B: Home and Garden Use

[Alternate brand names: QL Agri, QL Agri35]

Quillaja Extract

A Bio-Pesticide

*For Control of Plant Parasitic Nematodes and Plant Parasitic Fungi
in Vineyards, Orchards, Field Crops, Turf and Ornamentals*

Active Ingredient:

*Saponins of Quillaja saponaria.....8.60%

Other Ingredients 91.40%

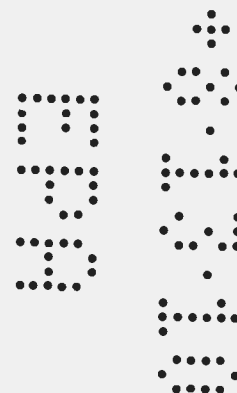
Total.....100.00%

*bidesmosidic derivatives of quillajic acid substituted with a trisaccharide at C-3 and an oligosaccharide in C-28

Manufactured for:
Desert King Chile
77 Antonio Bellet, Suite 401
Providencia, Santiago
Chile

EPA Reg. No.: 82572-1
EPA Est. No.: XXXXX-XX-XX

Net Contents: XX Gallons
Lot No.: XXX



Sublabel A: Agricultural and Commercial Use

Quillaja Extract

A Bio-Pesticide

*For Control of Plant Parasitic Nematodes and Plant Parasitic Fungi
in Vineyards, Orchards, Field Crops, Turf and Ornamentals*

Active Ingredient:

*Saponins of Quillaja saponaria.....8.60%

Other Ingredients 91.40%

Total..... 100.00%

*bidesmosidic derivatives of quillajic acid substituted with a trisaccharide at C-3 and an oligosaccharide in C-28

KEEP OUT OF REACH OF CHILDREN WARNING - ADVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

See back side for additional precautionary statements

Manufactured for:
Desert King Chile
77 Antonio Bellet, Suite 401
Providencia, Santiago

EPA Reg. No.: 82572-1
EPA Est. No.: XXXXX-XX-XX

Net Contents: XX Gallons

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye damage. Do not get in eyes or on clothing. Harmful if swallowed or absorbed through skin. Avoid contact with skin.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Protective eyewear
- Chemical-resistant gloves made of any waterproof material
- Shoes and socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Never apply material so as to contaminate eating or drinking area.
- Remove clothing/PPE immediately if product gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the Agency responsible for pesticide regulations.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label about personal protective equipment and the restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard. Do not enter or allow worker entry into treated areas without protective clothing during the restricted-entry interval (REI) of 24 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Chemical-resistant gloves made of any waterproof material
- Protective eyewear
- Shoes and socks

NON - AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of the product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural and ornamental plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

Mixing:

Fill tank with water to at least half full, then add recommended dosage of Quillaja Extract directly to the tank and continue filling. Agitation should be minimized in the tank (shut off paddle agitation if possible) to prevent foaming. To reduce foaming, an agricultural defoamer may be added to the tank mix. However, Quillaja Extract foam is very water soluble, will form a true solution, and should not be a concern for settling in the tank. Apply solution within three hours of mixing.

Compatibility:

Quillaja Extract is a water soluble botanical extract. It is physically compatible with most water based pesticides and liquid fertilizers providing the pH of the final solution is in a pH range of 3 to 8. Do not apply Quillaja Extract with any other product before testing for physical and chemical compatibility. To determine compatibility, pour the recommended proportions of the products into a suitable container, mix and wait for 30 minutes. If product remains mixed, it is considered physically compatible.

Not all tank mix combinations have been tested with this product. If compatibility of this product with another product is unknown, the mixture should be tested on a small scale.

Read and carefully observe the most restrictive of the labeling limitations and precautions of all product labels used in the tank mix. This product has properties similar to wetting agents and may enhance activity of some products as a wetting agent.

Application Methods: Consider the high solubility of this product when choosing a method of application and timing.

Foliar spray application (for powdery mildew): Apply by ground equipment to ensure complete and thorough coverage of foliage and/or crop. Contact of the disease organisms is essential for curative control.

Ground spray application (for nematodes and root rot): After area to be treated has been irrigated to field capacity, apply with a band or broadcast type sprayer, such as flat-fan or hollow cone nozzle tip system, to the soil surface. After application has been made it will be necessary to water with either drip, above ground sprinklers or reduced amount of furrow irrigation. Do not over irrigate following application of this product. Do not use flood irrigation to apply this product into the ground. Over irrigation will move the desired concentration of the product too quickly past the targeted root zone.

For ground sprayer application in orchards or around trees, begin application next to the tree trunk and spray at least 50% of soil area or the area under the canopy of the tree, whichever is greatest.

Shank injection application (for nematodes): After area to be treated has been irrigated to field capacity, apply by shank injection to areas where roots are present. Use a sufficient number of injectors to cover area to be treated. If shank application is applied at the root zone, minimal irrigation is required to assure that product covers root zone.

Chemigation application (for nematodes and root rot): Apply Quillaja Extract through the following types of systems. Do not apply this product through any other type of irrigation system.

- Low volume (ground or underground) drip, drip tape, strip tubing, micro-jet sprinklers, mini-sprinklers;
- Sprinkler including center pivot, lateral move, end tow, side (wheel) roll, solid set, or hand move;
- Furrow.

Check irrigation system and emitters to ensure all systems are operating normally before injecting Quillaja Extract. Lack of effectiveness or crop injury can result from non-uniform distribution of treated water.

If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers, chemigation experts or the Distributor of this product.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place. In addition, check local and state regulations regarding pesticide injection into public water systems.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Maintain the system's operating pressure low enough to prevent fogging and/or misting during applications. Inject Quillaja Extract into the irrigation system after the filter(s) or shut off the automatic back flush system in order to avoid back flushing of treated water.

Systems using a gravity flow pesticide dispensing system must meter the product into the water at the head of the field and downstream of the hydraulic discontinuity, such as a drop structure or weir box, to decrease potential for water source contamination from backflow if water flow stops.

Systems using a pressurized water and pesticide injection system must meet the following requirements:

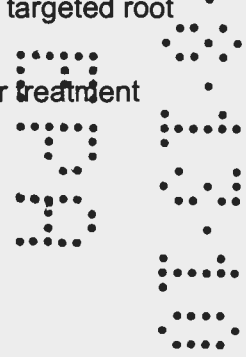
- The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
- The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of material that are compatible with pesticide and capable of being fitted with a system interlock.

It is highly recommended that the soil be irrigated to field capacity (down to two feet of soil) before pesticide application. For best results, inject Quillaja Extract into the irrigation line in the last quarter of the irrigation time. Continue irrigation until all lines are flushed. Maintain irrigation for enough time to assure this product has penetrated down into the targeted root zone. Do not over irrigate after applying this product. If excessive watering occurs immediately following application, this product may move down past the desired root zone due to its high water solubility. Do not irrigate for at least 24 hours following application of this product. Pest injury to the crop or lack of effectiveness in growth response may result from uneven distribution of this product during application.

Do not allow air in the line prior to injecting Quillaja Extract. The product's density will cause swelling of the line due to foam formation and prevent uptake of material. If a pesticide supply tank is used, follow directions listed under "Mixing" above. There generally will be some level of foam at the base of the wetted area until it dissolves (usually within 30 minutes after application, depending on temperature and amount of water following application).

If applied in heavy rainfall areas, avoid application during rain or when rain is forecasted within the next 24 hours that may exceed movement of this product past targeted root zone.

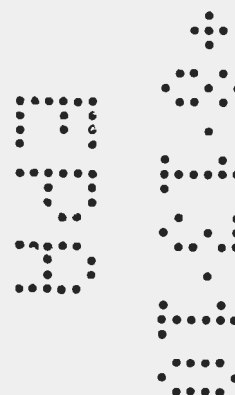
Do not apply when wind speed favors drift beyond the areas intended for treatment



Application Rates for Control of Nematodes

To control/suppress plant parasitic nematodes, apply Quillaja Extract to the full irrigated zone. For row crops, the irrigated zone is 30-50% of the row area. For orchards or around trees, apply from tree trunk to drip-line to cover at least 50% of soil area or the area under the canopy of the tree, whichever is greatest. Single applications should be made in the spring just prior to or during root flush, and again in the fall after harvest. For best results, multiple applications may be made in the spring, followed by a single application in the fall after harvest.

Crop	Remarks
<p>Berries: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Huckleberry, Loganberry, Raspberry (black and red)</p> <p>Citrus: Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo</p> <p>Grapes (raisin, table, wine)</p> <p>Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)</p> <p>Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince</p> <p>Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune</p>	<p>On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.</p>



Cole Crops:

Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables:

Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables:

Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables:

Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

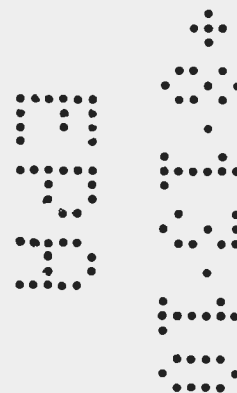
Strawberry

Apply 1-7 days preplant to the planting zone. Apply centered on the top of the row on pre-wetted soil. Follow with water to assure penetration of the product into the root zone.

On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.

On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.

For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.



<p>Bulb Vegetable: Garlic, Leek, Onion (including dry bulb, green and Welch), Shallot</p> <p>Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Ginseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)</p> <p>Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals</p>	<p>Apply prior to planting to row area to be planted. Apply centered on the top of the row on pre-wetted soil. Follow with water to assure penetration of the product into the root zone.</p> <p>On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.</p>
<p>Turfgrass Ornamental lawns, Golf courses, Sod farms</p> <p>For control of <i>Anguina pacifica</i> nematode only.</p>	<p>Apply 9 fl.oz. in 3-7 gallons water per 1,000 sq.ft. (equivalent to 3 gallons in 130-300 gallons water per acre) using a sprayer with a pressure nozzle tip applicator sufficient to penetrate into the lower part of the turf leaves where <i>Anguina pacifica</i> nematode galls are formed. Do not exceed a concentration of 1.5% solution of Quillaja Extract in any application.</p> <p>Repeat applications every 5-10 days. Additional applications to break the life cycle of the nematode should be repeated 2-4 times within 60 days to significantly reduce this pest problem in one season.</p> <p>Do not water turfgrass for at least 12 hours following application of Quillaja Extract. Quillaja Extract is water soluble and does not require additional water application through sprinkler following application.</p>

Application Rates for Control of Fungi

For control/suppression of **POWDERY MILDEW** in the following field and greenhouse grown crops, apply 1-4 pints Quillaja Extract per acre as a foliar spray in 50-100 gallons water per acre (equivalent to 0.5-1.5 fl.oz. in 1-2 gallons water per 1,000 sq.ft.) every 7-

10 days depending on severity of infection. A surfactant is not necessary, but the addition of a wetting agent, such as Yucca Ag-Aide™, may increase efficacy. Quillaja Extract may be tank mixed with Sterol Inhibitor type fungicides.

Berries and Small Fruits: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Grape (raisin, table, wine), Huckleberry, Kiwifruit, Loganberry, Raspberry (black and red), Strawberry

Bulb Vegetable: Garlic, Leek, Onion (including dry bulb, green and Welsh), Shallot

Cereal Grains: Barley, Buckwheat, Corn, Millet, (pearl and proso), Oats, Popcorn, Rice, Rye, Sorghum (milo), Teosinte, Triticale, Wheat, Wild rice

Cole Crops: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables: Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Legume Vegetables (succulent or dried): Bean (*Lupinus*, *Phaseolus* and *Vigna* spp.), Broad bean, Chickpea, Guar, Jackbean, Lablab bean, Lentil, Pea (*Pisum* spp.), Pigeon pea, Soybean, Sword bean

Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)

Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince

Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Gingseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Pluimcot, Prune

Subtropical Fruits: Banana, Date, Mango, Papaya, Pineapple

Additional crops: Hops, Mint (peppermint, spearmint), Tobacco

Herbs and Spices: Allspice, Angelica, Anise, Annatto, Balm, Basil, Borage, Burnet, Camomile, Caper buds, Caraway, Cardamom, Cassia, Catnip, Celery seed, Chervil, Chive, Cinnamon, Clary, Clove buds, Coriander, Coriander, Costmary, Culantro, Cumin, Curry, Dill, Fennel, Fenugreek, Grains of paradise, Horehound, Hyssop, Juniper berry, Lavender, Lemongrass, Lovage, Mace,

Marigold, Marjoram, Mustard, Nasturtium, Nutmeg, Parsley, Pennyroyal, Pepper, Poppy seed, Rosemary, Rue, Saffron, Sage, Savory, Sweet bay, Tansy, Tarragon, Thyme, Vanilla, Wintergreen, Woodruff, Wormwood

Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals

Turf: Ornamental lawns, golf courses and sod farms

For control/suppression of **PHYTOPHTHORA** and **PYTHIUM ROOT ROT** in the following field and greenhouse-grown crops, apply 2-4 quarts Quillaja Extract in 200 gallons water per acre (equivalent to 1.5-3 fl.oz. in 5 gallons water per 1,000 sq.ft.) to achieve a concentration of 2,500-5,000 ppm. Apply in early spring and fall, prior to root flush when soil temperatures are optimum for root infection. Apply to the entire root zone following, or at the end of, an irrigation cycle For best results, repeat application every 7 days, for up to 6 weeks. A surfactant is not necessary, but the addition of a wetting agent, such as Yucca Ag-Aide™, may increase efficacy. Quillaja Extract may be tank mixed with Sterol Inhibitor type fungicides.

Berries and Small Fruits: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Grape (raisin, table, wine), Huckleberry, Kiwifruit, Loganberry, Raspberry (black and red), Strawberry

Citrus: Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo,

Cole Crops: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables: Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)

Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince

Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Gingseng, Horseradish,

Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune

Additional crops: Avocado, Kiwifruit

Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals

Application Rates to Enhance Plant Growth and Yield

Under good growing conditions, absent of plant parasitic nematodes or plant parasitic fungi, Quillaja Extract is beneficial to plant growth and yield as described below.

Crop	Benefit	Rate per Acre	Comment
Grapes	Increased Fruit Yield and Root Development	1-2 quarts	Apply at root flush followed by 2-4 applications at 7-14 day intervals.
Citrus	Increased Root Development	1-2 gallons	Apply at root flush followed by 2 quarts/acre every 14 days for 4-6 weeks.
Strawberry	Increased Root Development	2-4 pts	Apply every 14 days for 8-10 weeks.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in cool dry area.

Pesticide Disposal: Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: ~~Un-Refillable~~ Nonrefillable container. Do not refill or reuse this container. Triple rinse (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SUBLABEL B: Home and Garden Label

[Alternate brand names: QL Agri, QL Agri35]

Quillaja Extract

A Bio-Pesticide

For Control of Plant Parasitic Nematodes and Home Orchards & Vineyards, Vegetable Gardens, Lawns and Ornamentals

Active Ingredient:

*Saponins of Quillaja saponaria..... 8.60%

Other Ingredients 91.40%

Total..... 100.00%

*bidesmosidic derivatives of quillajic acid substituted with a trisaccharide at C-3 and an oligosaccharide in C-28

KEEP OUT OF REACH OF CHILDREN

WARNING - ADVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID

If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If on skin

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for:
Lawn and Garden Products, Inc.
P.O. Box 35000
Fresno, CA 93745
(559) 499-2100
www.montereylawnandgarden.com

EPA Reg. No.: 82572-1
EPA Est. No.: XXXXX-XX-XX
Net Contents: XX Gallons
Lot No.: XXX

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye damage. Do not get in eyes or on clothing. Harmful if swallowed or absorbed through skin. Avoid contact with skin. Applicators should wear long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material and shoes plus socks. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Never apply material so as to contaminate eating or drinking area. Remove contaminated clothing and wash before reuse. Keep unprotected persons out of treated areas until sprays have dried.

ENVIRONMENTAL HAZARDS

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL BEFORE EACH USE.

For residential use in home orchards & vineyards, vegetable gardens, lawns and ornamentals.

APPLICATION METHODS

After area to be treated has been irrigated, apply with a band or broadcast type sprayer. After application has been made it may be necessary to water with either drip, above ground sprinklers or reduced amount of furrow irrigation. Do not over irrigate following application of this product. Do not use flood irrigation to apply this product into the ground. Over irrigation will move the desired concentration of the product too quickly past the targeted root zone.

For application in home orchards and around trees, begin application next to the tree trunk and spray at least 50% of soil area or the area under the canopy of the tree, whichever is greatest.

Apply solution within three hours of mixing.

If applied in heavy rainfall areas, avoid application during rain or when rain is forecasted within the next 24 hours that may exceed movement of this product past targeted root zone.

Do not apply when wind speed favors drift beyond the areas intended for treatment.

Application Rates for Control of Nematodes

To control/suppress plant parasitic nematodes, apply Quillaja Extract to the full irrigated area. For home orchards or around trees, apply from tree trunk to drip-line to cover at

least 50% of soil area or the area under the canopy of the tree, whichever is greatest. Single applications should be made in the spring just prior to or during root flush, and again in the fall after harvest. For best results, multiple applications may be made in the spring every 7 to 14 days for up to 10 weeks, followed by a single application in the fall after harvest.

<u>Use Site</u>	<u>Rate</u>
<u>Berries</u> (Not for use in California): <u>Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Huckleberry, Loganberry, Raspberry (black and red)</u>	<u>Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.</u>
<u>Citrus:</u> <u>Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo</u>	<u>Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.</u>
<u>Grapes</u>	<u>Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.</u>
<u>Nut Trees:</u> <u>Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)</u>	<u>Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.</u>
<u>Pome Fruit:</u> <u>Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince</u>	<u>Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.</u>
<u>Stone Fruit:</u> <u>Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune</u>	<u>Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.</u>
<u>Cole Crops:</u> <u>Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizune, Mustard greens, Mustard spinach, Rape greens</u>	<u>Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.</u>
<u>Cucurbit Vegetables:</u> <u>Chaoyote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, Crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable</u>	<u>Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.</u>

marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables:

Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.

Leafy Vegetables:

Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.

Strawberry

Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.

Bulb Vegetables:

Garlic, Leek, Onion (including dry bulb, green and Welch), Shallot

Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.

Root and Tuber Vegetables:

Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Ginseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.

Ornamentals:

Bare root, container, bedding and flowering plants, landscape, potted flowering, shade and flowering trees, woody ornamentals

Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.

Lawns:

For control of *Anguina pacifica* nematode only.

Apply 9 fl. oz. in 3-7 gallons of water per 1,000 sq. ft. using a sprayer with a pressure nozzle tip applicator sufficient to penetrate into the lower part of the turf leaves where *Anguina pacifica* nematode galls are formed. Do not exceed a concentration of 1.5% Quillaja Extract in any application.

Repeat applications every 5-10 days. Additional applications to break the life cycle of the nematode should be

repeated 2-4 times within 60 days to significantly reduce this pest problem in one season.

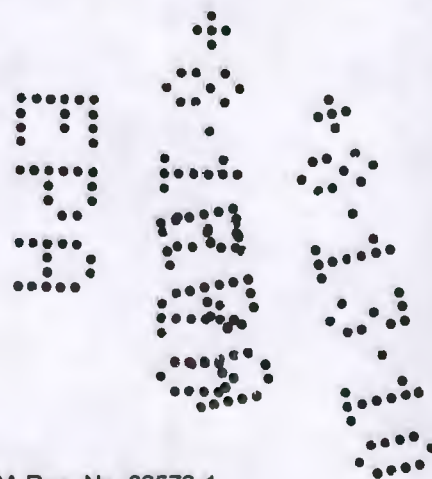
Do not water lawn for at least 12 hours following application of Quillaja Extract. Quillaja Extract is water soluble and does not require additional water application through sprinkler following application.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

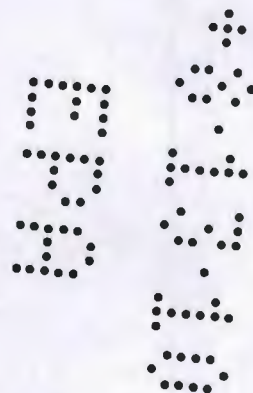
Pesticide Storage: To be stored in original container in a cool, well-ventilated areas inaccessible to children and pets. Store above 40°F.

Pesticide/Container Disposal: Nonrefillable container. Do not refill or reuse this container. If empty: Place in trash or offer for recycling in available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.



LIMITED WARRANTY

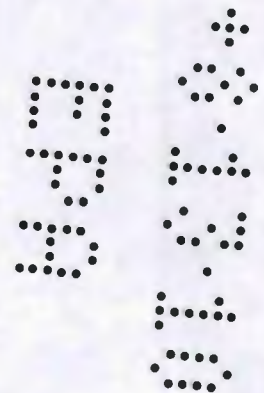
Desert King Chile warrants that this product conforms to the chemical description on the label and is reasonable fit for the purposes set forth in the Complete Directions for Use label booklet ("Directions") when used in accordance with those Directions under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MECHANABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.



-[] indicates s optional text

Optional Label Claims:

- Controls and/or Suppresses certain foliar diseases such as Powdery Mildew(s)
- Suppresses [Nematodes], [Powdery Mildew]
- For use also on Vegetable Crops Such as: Carrots, Peppers, Tomatoes, Broccoli, Squash, and Beets.



MATERIAL TO BE ADDED TO JACKET

REG #: 82572-1

Description: Notification - Accepted

if applicable, check all that are attached:		Send to CSC
<input type="checkbox"/>	new stamped accepted label	
<input type="checkbox"/>	new CSF	
<input checked="" type="checkbox"/>	notification	
<input type="checkbox"/>	other:	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer: Colin Walsh Date: 7/27/2010

Phone: (703) 308-0298 Division: BPPD

Receipt for Section 3

S: 678564

Re: ☐ New ☒ Yes ☐ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Notification

Company: 62572 DESERT KING CHILE, LTD.

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 62572-1 Product Name: QUILLAJA EXTRACT

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 13-Jul-2010

ie

OPP Rec'd Date: 13-Jul-2010

ie

Front End Date: 13-Jul-2010

ie

Risk Manager Send Date: 16-Jul-2010

ie

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

with Ingredient: ☐

Receipt Description:

adding 2 alt brand names

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Paper Label

View/Edit

Rec'd
AAB
7/16/10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 27, 2010

Desert King Chile, Ltd.
c/o Heather R. Bjornson
Technology Sciences Group, Inc.
1150 18th Street, N.W., Suite 1000
Washington, D.C. 20036

RE: Product Name: Quillaja Extract
EPA Reg. No.: 82572-1
Application for Label Notification dated July 13, 2010 to add the alternate
brand names "QL Agri" and "QL Agri35".

Dear Ms. Bjornson:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under PR Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification Accepted" and will be placed accordingly in our records.

If you have any questions concerning this action, please feel free to contact Mr. Colin Walsh at (703) 308-0298 or via email at walsh.colin@epa.gov.

Sincerely,

Linda A. Hollis

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)

Quillaja Extract

A Bio-Pesticide

Notification Accepted

Date: JUL 27 2010

Reviewer: C. Walsh

[Alternate brand names: QL Agri, QL Agri35]

*For Control of Plant Parasitic Nematodes and Plant Parasitic Fungi
in Vineyards, Orchards, Field Crops, Turf and Ornamentals*

Active Ingredient:

*Saponins of Quillaja saponaria.....8.60%

Other Ingredients 91.40%

Total..... 100.00%

*bidesmosidic derivatives of quillajic acid substituted with a trisaccharide at C-3 and an oligosaccharide in C-28

KEEP OUT OF REACH OF CHILDREN

WARNING - ADVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

See back side for additional precautionary statements

Manufactured for:
Desert King Chile
77 Antonio Bellet, Suite 401
Providencia, Santiago
Chile

EPA Reg. No.: 82572-1
EPA Est. No.: XXXXX-XX-XX

Net Contents: XX Gallons
Batch Code: XXX

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye damage. Do not get in eyes or on clothing. Harmful if swallowed or absorbed through skin. Avoid contact with skin.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Protective eyewear
- Chemical-resistant gloves made of any waterproof material
- Shoes and socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Never apply material so as to contaminate eating or drinking area.
- Remove clothing/PPE immediately if product gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the Agency responsible for pesticide regulations.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label about personal protective equipment and the restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard. Do not enter or allow worker entry into treated areas without protective clothing during the restricted-entry interval (REI) of 24 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Chemical-resistant gloves made of any waterproof material
- Protective eyewear
- Shoes and socks

NON - AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of the product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural and ornamental plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

Mixing:

Fill tank with water to at least half full, then add recommended dosage of Quillaja Extract directly to the tank and continue filling. Agitation should be minimized in the tank (shut off paddle agitation if possible) to prevent foaming. To reduce foaming, an agricultural defoamer may be added to the tank mix. However, Quillaja Extract foam is very water soluble, will form a true solution, and should not be a concern for settling in the tank. Apply solution within three hours of mixing.

Compatibility:

Quillaja Extract is a water soluble botanical extract. It is physically compatible with most water based pesticides and liquid fertilizers providing the pH of the final solution is in a pH range of 3 to 8. Do not apply Quillaja Extract with any other product before testing for physical and chemical compatibility. To determine compatibility, pour the recommended proportions of the products into a suitable container, mix and wait for 30 minutes. If product remains mixed, it is considered physically compatible.

Not all tank mix combinations have been tested with this product. If compatibility of this product with another product is unknown, the mixture should be tested on a small scale.

Read and carefully observe the most restrictive of the labeling limitations and precautions of all product labels used in the tank mix. This product has properties similar to wetting agents and may enhance activity of some products as a wetting agent.

Application Methods: Consider the high solubility of this product when choosing a method of application and timing.

Foliar spray application (for powdery mildew): Apply by ground equipment to ensure complete and thorough coverage of foliage and/or crop. Contact of the disease organisms is essential for curative control.

Ground spray application (for nematodes and root rot): After area to be treated has been irrigated to field capacity, apply with a band or broadcast type sprayer, such as flat-fan or hollow cone nozzle tip system, to the soil surface. After application has been made it will be necessary to water with either drip, above ground sprinklers or reduced amount of furrow irrigation. Do not over irrigate following application of this product. Do not use flood irrigation to apply this product into the ground. Over irrigation will move the desired concentration of the product too quickly past the targeted root zone.

For ground sprayer application in orchards or around trees, begin application next to the tree trunk and spray at least 50% of soil area or the area under the canopy of the tree, whichever is greatest.

Shank injection application (for nematodes): After area to be treated has been irrigated to field capacity, apply by shank injection to areas where roots are present. Use a sufficient number of injectors to cover area to be treated. If shank application is applied at the root zone, minimal irrigation is required to assure that product covers root zone.

Chemigation application (for nematodes and root rot): Apply Quillaja Extract through the following types of systems. Do not apply this product through any other type of irrigation system.

- Low volume (ground or underground) drip, drip tape, strip tubing, micro-jet sprinklers, mini-sprinklers;
- Sprinkler including center pivot, lateral move, end tow, side (wheel) roll, solid set, or hand move;
- Furrow.

Check irrigation system and emitters to ensure all systems are operating normally before injecting Quillaja Extract. Lack of effectiveness or crop injury can result from non-uniform distribution of treated water.

If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers, chemigation experts or the Distributor of this product.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place. In addition, check local and state regulations regarding pesticide injection into public water systems.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Maintain the system's operating pressure low enough to prevent fogging and/or misting during applications. Inject Quillaja Extract into the irrigation system after the filter(s) or shut off the automatic back flush system in order to avoid back flushing of treated water.

Systems using a gravity flow pesticide dispensing system must meter the product into the water at the head of the field and downstream of the hydraulic discontinuity, such as a drop structure or weir box, to decrease potential for water source contamination from backflow if water flow stops.

Systems using a pressurized water and pesticide injection system must meet the following requirements:

- The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
- The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of material that are compatible with pesticide and capable of being fitted with a system interlock.

It is highly recommended that the soil be irrigated to field capacity (down to two feet of soil) before pesticide application. For best results, inject Quillaja Extract into the irrigation line in the last quarter of the irrigation time. Continue irrigation until all lines are flushed. Maintain irrigation for enough time to assure this product has penetrated down into the targeted root zone. Do not over irrigate after applying this product. If excessive watering occurs immediately following application, this product may move down past the desired root zone due to its high water solubility. Do not irrigate for at least 24 hours following application of this product. Pest injury to the crop may result from uneven distribution of this product during application.

Do not allow air in the line prior to injecting Quillaja Extract. The product's density will cause swelling of the line due to foam formation and prevent uptake of material. If a pesticide supply tank is used, follow directions listed under "Mixing" above. There generally will be some level of foam at the base of the wetted area until it dissolves (usually within 30 minutes after application, depending on temperature and amount of water following application).

If applied in heavy rainfall areas, avoid application during rain or when rain is forecasted within the next 24 hours that may exceed movement of this product past targeted root zone.

Do not apply when wind speed favors drift beyond the areas intended for treatment

Application Rates for Control of Nematodes

To control/suppress plant parasitic nematodes, apply Quillaja Extract to the full irrigated zone. For row crops, the irrigated zone is 30-50% of the row area. For orchards or around trees, apply from tree trunk to drip-line to cover at least 50% of soil area or the area under the canopy of the tree, whichever is greatest. Single applications should be made in the spring just prior to or during root flush, and again in the fall after harvest. For best results, multiple applications may be made in the spring, followed by a single application in the fall after harvest.

Crop	Remarks
Berries: (Not for Use in California) Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Huckleberry, Loganberry, Raspberry (black and red)	On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.
Citrus: Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo	On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.
Grapes (raisin, table, wine)	For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.
Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)	
Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince	
Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune	

Cole Crops:

Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables:

Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables:

Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables:

Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Strawberry

Apply 1-7 days preplant to the planting zone. Apply centered on the top of the row on pre-wetted soil. Follow with water to assure penetration of the product into the root zone.

On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.

On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.

For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.

<p>Bulb Vegetable: Garlic, Leek, Onion (including dry bulb, green and Welch), Shallot</p> <p>Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Ginseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)</p> <p>Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals</p>	<p>Apply prior to planting to row area to be planted. Apply centered on the top of the row on pre-wetted soil. Follow with water to assure penetration of the product into the root zone.</p> <p>On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.</p>
<p>Turfgrass Ornamental lawns, Golf courses, Sod farms</p> <p>For control of <i>Anguina pacifica</i> nematode only.</p>	<p>Apply 9 fl.oz. in 3-7 gallons water per 1,000 sq.ft. (equivalent to 3 gallons in 130-300 gallons water per acre) using a sprayer with a pressure nozzle tip applicator sufficient to penetrate into the lower part of the turf leaves where <i>Anguina pacifica</i> nematode galls are formed. Do not exceed a concentration of 1.5% solution of Quillaja Extract in any application.</p> <p>Repeat applications every 5-10 days. Additional applications to break the life cycle of the nematode should be repeated 2-4 times within 60 days to significantly reduce this pest problem in one season.</p> <p>Do not water turfgrass for at least 12 hours following application of Quillaja Extract. Quillaja Extract is water soluble and does not require additional water application through sprinkler following application.</p>

Application Rates for Control of Fungi

For control/suppression of **POWDERY MILDEW** in the following field and greenhouse-grown crops, apply 1-4 pints Quillaja Extract per acre as a foliar spray in 50-100 gallons water per acre (equivalent to 0.5-1.5 fl.oz. in 1-2 gallons water per 1,000 sq.ft.) every 7-

Desert King – Quillaja Extract: EPA Reg. No. 82572-1
Label Version (9); July 13, 2010
Page 8 of 13

10 days depending on severity of infection. A surfactant is not necessary, but the addition of a wetting agent, such as Yucca Ag-Aide™, may increase efficacy. Quillaja Extract may be tank mixed with Sterol Inhibitor type fungicides.

Berries and Small Fruits: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Grape (raisin, table, wine), Huckleberry, Kiwifruit, Loganberry, Raspberry (black and red), Strawberry

Bulb Vegetable: Garlic, Leek, Onion (including dry bulb, green and Welch), Shallot

Cereal Grains: Barley, Buckwheat, Corn, Millet, (pearl and proso), Oats, Popcorn, Rice, Rye, Sorghum (milo), Teosinte, Triticale, Wheat, Wild rice

Cole Crops: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables: Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Legume Vegetables (succulent or dried): Bean (*Lupinus*, *Phaseolus* and *Vigna* spp.), Broad bean, Chickpea, Guar, Jackbean, Lablab bean, Lentil, Pea (*Pisum* spp.), Pigeon pea, Soybean, Sword bean

Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)

Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince

Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Gingseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune

Subtropical Fruits: Banana, Date, Mango, Papaya, Pineapple

Additional crops: Hops, Mint (peppermint, spearmint), Tobacco

Herbs and Spices: Allspice, Angelica, Anise, Annatto, Balm, Basil, Borage, Burnet, Camomile, Caper buds, Caraway, Cardamom, Cassia, Catnip, Celery seed, Chervil, Chive, Cinnamon, Clary, Clove buds, Coriander, Coriander, Costmary, Culantro, Cumin, Curry, Dill, Fennel, Fenugreek, Grains of paradise, Horehound, Hyssop, Juniper berry, Lavender, Lemongrass, Lovage, Mace,

Marigold, Marjoram, Mustard, Nasturtium, Nutmeg, Parsley, Pennyroyal, Pepper, Poppy seed, Rosemary, Rue, Saffron, Sage, Savory, Sweet bay, Tansy, Tarragon, Thyme, Vanilla, Wintergreen, Woodruff, Wormwood

Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals

Turf: Ornamental lawns, golf courses and sod farms

For control/suppression of **PHYTOPHTHORA** and **PYTHIUM ROOT ROT** in the following field and greenhouse-grown crops, apply 2-4 quarts Quillaja Extract in 200 gallons water per acre (equivalent to 1.5-3 fl.oz. in 5 gallons water per 1,000 sq.ft.) to achieve a concentration of 2,500-5,000 ppm. Apply in early spring and fall, prior to root flush when soil temperatures are optimum for root infection. Apply to the entire root zone following, or at the end of, an irrigation cycle For best results, repeat application every 7 days, for up to 6 weeks. A surfactant is not necessary, but the addition of a wetting agent, such as Yucca Ag-Aide™, may increase efficacy. Quillaja Extract may be tank mixed with Sterol Inhibitor type fungicides.

Berries and Small Fruits: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Grape (raisin, table, wine), Huckleberry, Kiwifruit, Loganberry, Raspberry (black and red), Strawberry

Citrus: Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo,

Cole Crops: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables: Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)

Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince

Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Gingseng, Horseradish,

Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune

Additional crops: Avocado, Kiwifruit

Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals

Application Rates to Enhance Plant Growth and Yield

Under good growing conditions, absent of plant parasitic nematodes or plant parasitic fungi, Quillaja Extract is beneficial to plant growth and yield as described below.

Crop	Benefit	Rate per Acre	Comment
Grapes	Increased Fruit Yield and Root Development	1-2 quarts	Apply at root flush followed by 2-4 applications at 7-14 day intervals.
Citrus	Increased Root Development	1-2 gallons	Apply at root flush followed by 2 quarts/acre every 14 days for 4-6 weeks.
Strawberry	Increased Root Development	2-4 pts	Apply every 14 days for 8-10 weeks.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in cool dry area.

Pesticide Disposal: Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Un-Refillable Container. Do not refill or reuse this container. Triple rinse (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

LIMITED WARRANTY

Desert King Chile warrants that this product conforms to the chemical description on the label and is reasonable fit for the purposes set forth in the Complete Directions for Use label booklet ("Directions") when used in accordance with those Directions under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

[] indicate optional text

Optional Label Claims:

- Controls and/or Suppresses certain foliar diseases such as Powdery Mildew(s)
- Suppresses [Nematodes], [Powdery Mildew]
- For use also on Vegetable Crops Such as: Carrots, Peppers, Tomatoes, Broccoli, Squash, and Beets.



WASHINGTON

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Linda Hollis

Chief, Biopesticide and Pollution Prevention Division

Office of Pesticide Programs

Environmental Protection Agency

Room S-4900, One Potomac Yard

2777 South Crystal Drive

Arlington, VA 22202-4501

July 13, 2010

RE: Quillaja Extract (EPA Reg. No. 82572-1)

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

Notification per PR Notice 98-10

Dear Ms. Hollis:

Technology Sciences Group, on behalf of Desert King Chile, is submitting the enclosed notification to add two alternate brand names to the above referenced product.

Please do not hesitate to contact me directly with any questions and/or concerns.

Sincerely,

Heather R. Bjornson

Regulatory Agent for Desert King Chile/Desert King International

CANADA

275 Slater Street

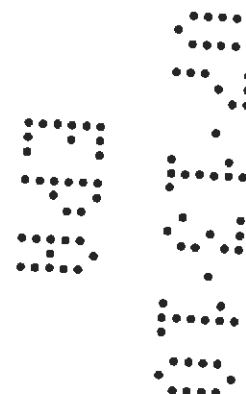
Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82572-1	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Quillaja Extract	PM# 91 BPPD/Biochemical Pesticides	
5. Name and Address of Applicant (Include ZIP Code) Desert King Chile, Ltd. Antoinio Bellet 77 Of 401 Providencia, Santiago, Chile <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	Notification Accepted JUL 27 2010 Date: Reviewer: C. Walsh
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This notification is to add two alternate brand names per PR Notice 98-10 and is not subject to PRIA. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 5 gal pale; 30 & 55 g drum; 270g tote		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Heather R. Bjornson, Technology Sciences Group, Inc.		Title Regulatory Consultant		Telephone No. (Include Area Code) (202) 828-8945	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant to Desert King Chile			
4. Typed Name Heather R. Bjornson		5. Date July 13, 2010			

MATERIAL TO BE ADDED TO JACKET

REG #: 82572-1

Description: correspondence

if applicable, check all that are attached:		Send to CSC
<input type="checkbox"/>	new stamped accepted label	
<input type="checkbox"/>	new CSF	
<input type="checkbox"/>	notification	
<input checked="" type="checkbox"/>	other: extension request	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer: John Fournier Date: 6/30/2010

Phone: (703) 308-0169 Division: BPPD

JUN 28 2010

Heather R. Bjornson, Regulatory Agent
Technology Sciences Group, Inc.
1150 18th Street, N.W. Ste. 1000
Washington, DC 20036

Subject: Quillaja Extract (EPA Registration No. 82572-1)
Condition of Registration: Efficacy Data
Extension Request Letter dated June 10, 2010

Dear Ms. Bjornson:

The Biopesticides and Pollution Prevention Division (BPPD) is in receipt of your letter in which you request an extension of one month for the submission of efficacy data. This efficacy data, which is required as a condition of registration for the above-referenced product, was due to the Agency by June 15, 2010. By way of this letter, the Agency agrees to extend the submission deadline for your efficacy data to July 15, 2010.

If you have any questions please contact John Fournier at 703-308-0169, or by email at fournier.john@epa.gov.

Sincerely,



Linda A. Hollis, Chief,
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

CONCURRENCES							
SYMBOL	7511P	7511P					
SURNAME	Fournier	COLE					
DATE	25 Jun 10	6/25/10					



Re: Fw: Desert King - Extension Request

Linda Hollis o John Fournier

06/10/2010 12:41 PM

ok, grant the extension. She needs an official request.

Linda A. Hollis, MS
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

John Fournier

Hi Linda, This one is non-PRIA. There was a co...

06/10/2010 12:39:19 PM

From: John Fournier/DC/USEPA/US
To: Linda Hollis/DC/USEPA/US@EPA
Date: 06/10/2010 12:39 PM
Subject: Re: Fw: Desert King - Extension Request

Hi Linda,

This one is non-PRIA. There was a conditional registration issued in July 2007 for Quillaja and efficacy data we required within one year, by July 2008. They didn't make the deadline and were granted an extension to January 2009. When they submitted the data in January, Jacob found it to be deficient. We then gave them another six months to resubmit the data, due June 15, 2010. They are now requesting an extension of an additional 30 days, to July 15.

John Fournier
Regulatory Action Leader, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
fournier.john@epa.gov
(703) 308-0169 (phone)
(703) 305-0118 (fax)
<http://www.epa.gov/pesticides>

Linda Hollis where does this put the pria date, how close are...

06/10/2010 12:26:59 PM

John Fournier Linda, Will we grant this request for another e...

06/10/2010 09:04:53 AM



WASHINGTON

1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Linda Hollis
John Fournier
Biopesticide and Pollution Prevention Division
Office of Pesticide Programs
Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

June 10, 2010

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

RE: Quillaja Extract (EPA Reg. No. 82572-1)

**Extension request for responding to the EPA Letter dated
October 28, 2009**

Dear Ms. Hollis:

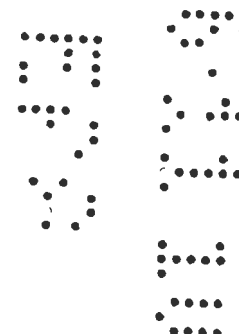
Technology Sciences Group, on behalf of Desert King Chile, is submitting this request to extend the response time for an additional one month for responding to the above referenced letter. With this response, we are requesting the deadline to submit the efficacy response to be July 15, 2010. We are working on a way to properly address this concern.

CANADA

275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

Sincerely,

Heather R. Bjornson
Regulatory Agent for Desert King Chile/Desert King International



Receipt for Section 3

S: 876485

Reg. Amendment: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☐ Yes ☒ No

Company: 82572 DESERT KING CHILE, LTD

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 82572-1

Product Name: QUILLAJA EXTRACT

Chemical:

Me Too
Section3:Me Too Product
Name:

Application Date: 10-Jun-2010



OPP Rec'd Date: 11-Jun-2010



Front End Date: 11-Jun-2010



Risk Manager Send Date: 14-Jun-2010



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐New Ingredient: ☐

Receipt Description:

extension request.

Form #: ☐

Signature Date:

Form #: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Other

extension request.

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:

Decs# 406151

Rec'd
6/15/10
99 ACB

MATERIAL TO BE ADDED TO JACKET

REG #: 82572-1

Description: Quill/7JA Extract

if applicable, check all that are attached:		Send to CSC
<input type="checkbox"/>	new stamped accepted label	
<input type="checkbox"/>	new CSF	
<input type="checkbox"/>	notification	
<input checked="" type="checkbox"/>	other: <u>Label Amendment (NOT Accepted)</u>	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer: Menyon Adams Date: 01/11/10

Phone: (703) 347-8496 Division: BPPD

Receipt for Section 3

S: ☐ Yes ☒ No

Regulatory Type: Fee For Service: ☐ Yes ☒ No

Application Type: Billable: ☐ Yes ☒ No

Company: ☒ V

Risk Manager:

Product #: Product Name:

Me Too Me Too

Section3: Product Name:

Application Date: ☒ OPP Rec'd Date: ☒

Front End Date: ☒ Risk Manager Send Date: ☒

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ Receipt Description:

Form A: ☐ Signature Date: Form B: ☐ Signature Date:

Print Letter
Enter More Information
Tracking

Receipt Content
Paper Label

View/Edit

300, Fast Track Amendment Rec'd # 421423. Due Date: 12/28/09

Meayon,

The registrant is adding home & garden use for this a.i. Check OPPIN & see if this a.i. has any residential use sites. If it does not then it may be eligible for the 30 day connect period.

Andy

Received
MRS
10/2/09
None or Receipt (due)

Rec'd
OCT - 2 2009
ACB
~~OCT - 1 2009~~

JAN 11 2010

Heather R. Bjornson
Regulatory Consultant for Desert King Chile
Technology Sciences Group, Inc.
1150 18th Street, N.W., Suite 1000
Washington, DC 20036

Subject: Labeling Amendment
EPA Reg No.: 82572-1
Your Application Dated September 28, 2009
Decision #: 421423

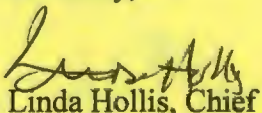
Dear Ms. Bjornson:

The amendment to add residential uses to the product label submitted in connection with registration under FIFRA as amended is not acceptable. FIFRA section 3(c)(3)(B)(II) set forth the conditions under which the Agency interprets an application submission to be considered as a Fast track action. In light of this regulation, we have therefore determined that this request will be considered as an amendment to be submitted under PRIA category B650, which carries a 6-month time frame.

This determination has been made based on the nature of your request which includes a first residential use for this active ingredient. In consideration of this request, the Agency will need to update the risk assessment and this action will undergo the public participation process. Therefore, you will need to submit a new request under PRIA.

If you have any questions concerning this action, please feel free to contact Ms. Menyon Adams at (703) 347-8496 or email at adams.menyon@epa.gov.

Sincerely,


Linda Hollis, Chief

Biochemical Pesticides Branch

Biopesticides and Pollution Prevention
CONCURRENCES
Division (7511P)

SYMBOL	NSIP						
SURNAME	Adams						
DATE	1/11/10						



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 1, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

HEATHER R. BJORNSON
TECHNOLOGY SCIENCES GROUP, INC.
DESERT KING CHILE, LTD.
1150 18TH ST., NW, SUITE 1000
WASHINGTON, DC 20036-

PRODUCT NAME: QUILLAJA EXTRACT
COMPANY NAME: DESERT KING CHILE, LTD.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 82572-1
EPA RECEIPT DATE: 09/29/09

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 308-8733.

Sincerely,
Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



WASHINGTON

1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Linda Hollis
Chief, Biopesticide and Pollution Prevention Division
Office of Pesticide Programs
Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

September 28, 2008

RE: Quillaja Extract (EPA Reg. No. 82572-1)

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

Fast-track label amendment

Dear Ms. Hollis:

Technology Sciences Group, on behalf of Desert King Chile, is submitting the enclosed fast-track label amendment to make a master label and add a Home and Garden sublabel.

You will find the following in support of this amendment:

- 1) Amendment application form,
- 2) One redline version of the label, and
- 3) Three clean copies of the revised label.

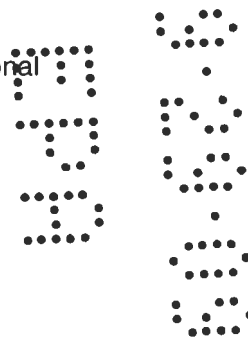
CANADA

275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

Please do not hesitate to contact me directly with any questions and/or concerns.

Sincerely,

Heather R. Bjornson
Regulatory Agent for Desert King Chile/Desert King International





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82572-1	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Quillaja Extract	PM# BPPD/Biochemical Pesticides	
5. Name and Address of Applicant (Include ZIP Code) Desert King Chile, Ltd. Antoinio Bellet 77 Of 401 Providencia, Santiago, Chile <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is a fast-track label amendment to make a mater label and to add home and garden uses.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 5 gal pale; 30 & 55 g drum; 270g tote		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Heather R. Bjornson, Technology Sciences Group, Inc.		Title Regulatory Consultant	
		Telephone No. (Include Area Code) (202) 828-8945	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant to Desert King Chile	
4. Typed Name Heather R. Bjornson		5. Date September 28, 2009	

Fee for Service

{859237B~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☒ BPPD
- ☐ RD

Risk Mgr. 91

Receipt No.

S-

859237

EPA File Symbol/Reg. No.

82572-1

Pin-Punch Date:

9/28/2009

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Andrew Byceland

Date: 9/30/09

Remarks:

300. Label Amendment

BPPD Label Amendment Checklist

Fast Track ☒ and PRIA Actions B680 ☐, B730 ☐ B900

EPA Reg. No.: 82572-1

RAL: Menyon Adams

Application Date: 09/28/09

#	Check list Item	Yes	No
1.	Application Form (EPA Form 8570-1) - signed & complete, including package type? IF NO, STOP! Call applicant and have them correct application and resubmit.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2.	Final printed labeling received for previous action? IF NO, STOP! E-mail applicant and request final printed labeling (FPL).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.	Data and Data Matrix present. (EPA Form 8570-35) NA <input type="checkbox"/> If Fast Track, check to see if original registration supported by data, formulators exemption, etc.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
a.	Using Selective Method? [IF NO, SKIP to next item since data matrix required for selective method.]	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b.	Complete Data Matrix supporting both the product registration and the proposed amendment. Minimum Data Matrix for registration includes: Product specific Acute Toxicity and Product Chemistry data, plus Efficacy data for public health pests claimed on label.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c.	Adequate product specific data?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d.	Registered source used for active ingredient? IF YES, SKIP to ITEM 4. (If active ingredient is from a registered source (manufacturing-use product), generic data should be satisfied by registered source.) IF NO or if use not supported by registered source , generic data is necessary.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
e.	If new data submitted: data passed PR Notice 86-5 for formatting and MRID # assigned?	<input type="checkbox"/>	<input type="checkbox"/>
f.	Public copy of Data Matrix provided? (PRN 98-5)	<input type="checkbox"/>	<input type="checkbox"/>
4.	Certification with Respect to Citation of Data present. (EPA Form 8570-34): See 40 CFR 152.80-98 and PR Notice 98-5 [If no data are required or submitted, a Certification with Respect to Citation of Data form isn't needed. This is often true for minor amendments.] NA <input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
a.	Did applicant check a Method of Support?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b.	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c.	Is the form signed and dated?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d.	Check form and Data Matrix. Are Exclusive Use data cited from other sources?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	IF YES , is the required authorization letter included in application? NA <input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.	Label(s) Review Menyon Adams Date of Label Review:		
a.	Label(s) in conformance with current <i>Label Review Manual</i> and appropriate REDS.	<input type="checkbox"/>	<input type="checkbox"/>
b.	Labeling statements and claims are supported by Acute Toxicity, Product Chemistry data (or acceptable waivers). Acceptable efficacy studies support public health pests claimed on label.	<input type="checkbox"/>	<input type="checkbox"/>
c.	Nominal concentration of active ingredient shown in ingredients statement.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d.	Viability included as sub-statement of Ingredient Statement (if live microbial, i.e., cfu/gram). N/A	<input type="checkbox"/>	<input type="checkbox"/>
e.	Storage and disposal instructions agree with container types listed on application form.	<input type="checkbox"/>	<input type="checkbox"/>
f.	Unique Product Name for Same Company (Check OPPIN).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
g.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? IF YES , RAL must evaluate label use directions for compliance with 40 CFR 180.1071.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
h.	Does label bear "National Organic Program" (PR Notice 2003-1) or OMRI claims?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	If YES, National Organic Program or OMRI claims approved by Bob Torla? NA <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i.	Labeling is acceptable. Corrections or changes are NOT necessary.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
j.	Comments: If label included data, is DER attached?	<input type="checkbox"/>	<input type="checkbox"/>

Master Label:
Sublabel A: Agricultural and Commercial Use
Sublabel B: Home and Garden Use

Quillaja Extract

A Bio-Pesticide

*For Control of Plant Parasitic Nematodes and Plant Parasitic Fungi
in Vineyards, Orchards, Field Crops, Turf and Ornamentals*

Active Ingredient:

*Saponins of Quillaja saponaria 8.60%

Other Ingredients 91.40%

Total 100.00%

*bidesmosidic derivatives of quillajic acid substituted with a trisaccharide at C-3 and an oligosaccharide in C-28

Manufactured for:
Desert King Chile
77 Antonio Bellet, Suite 401
Providencia, Santiago
Chile

EPA Reg. No.: 82572-1
EPA Est. No.: XXXXX-XX-XX

Net Contents: XX Gallons
Batch Code: XXX



Sublabel A: Agricultural and Commercial Use

Quillaja Extract

A Bio-Pesticide

*For Control of Plant Parasitic Nematodes and Plant Parasitic Fungi
in Vineyards, Orchards, Field Crops, Turf and Ornamentals*

Active Ingredient:

*Saponins of Quillaja saponaria 8.60%

Other Ingredients 91.40%

Total 100.00%

*bidesmosidic derivatives of quillajic acid substituted with a trisaccharide at C-3 and an oligosaccharide in C-28

KEEP OUT OF REACH OF CHILDREN

WARNING - ADVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

See back side for additional precautionary statements

Manufactured for:
Desert King Chile
77 Antonio Bellet, Suite 401
Providencia, Santiago
Chile

EPA Reg. No.: 82572-1
EPA Est. No.: XXXXX-XX-XX

Net Contents: XX Gallons
Batch Code: XXX

Desert King – Quillaja Extract: EPA Reg. No. 82572-1
Label Version (8); September 28, 2009
Page 2 of 19

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye damage. Do not get in eyes or on clothing. Harmful if swallowed or absorbed through skin. Avoid contact with skin.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Protective eyewear
- Chemical-resistant gloves made of any waterproof material
- Shoes and socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Never apply material so as to contaminate eating or drinking area.
- Remove clothing/PPE immediately if product gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the Agency responsible for pesticide regulations.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label about personal protective equipment and the restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard. Do not enter or allow worker entry into treated areas without protective clothing during the restricted-entry interval (REI) of 24 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Chemical-resistant gloves made of any waterproof material
- Protective eyewear
- Shoes and socks

NON - AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of the product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural and ornamental plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

Mixing:

Fill tank with water to at least half full, then add recommended dosage of Quillaja Extract directly to the tank and continue filling. Agitation should be minimized in the tank (shut off paddle agitation if possible) to prevent foaming. To reduce foaming, an agricultural defoamer may be added to the tank mix. However, Quillaja Extract foam is very water soluble, will form a true solution, and should not be a concern for settling in the tank. Apply solution within three hours of mixing.

Compatibility:

Quillaja Extract is a water soluble botanical extract. It is physically compatible with most water based pesticides and liquid fertilizers providing the pH of the final solution is in a pH range of 3 to 8. Do not apply Quillaja Extract with any other product before testing for physical and chemical compatibility. To determine compatibility, pour the recommended proportions of the products into a suitable container, mix and wait for 30 minutes. If product remains mixed, it is considered physically compatible.

Not all tank mix combinations have been tested with this product. If compatibility of this product with another product is unknown, the mixture should be tested on a small scale.

Read and carefully observe the most restrictive of the labeling limitations and precautions of all product labels used in the tank mix. This product has properties similar to wetting agents and may enhance activity of some products as a wetting agent.

Application Methods: Consider the high solubility of this product when choosing a method of application and timing.

Foliar spray application (for powdery mildew): Apply by ground equipment to ensure complete and thorough coverage of foliage and/or crop. Contact of the disease organisms is essential for curative control.

Ground spray application (for nematodes and root rot): After area to be treated has been irrigated to field capacity, apply with a band or broadcast type sprayer, such as flat-fan or hollow cone nozzle tip system, to the soil surface. After application has been made it will be necessary to water with either drip, above ground sprinklers or reduced amount of furrow irrigation. Do not over irrigate following application of this product. Do not use flood irrigation to apply this product into the ground. Over irrigation will move the desired concentration of the product too quickly past the targeted root zone.

For ground sprayer application in orchards or around trees, begin application next to the tree trunk and spray at least 50% of soil area or the area under the canopy of the tree, whichever is greatest.

Shank injection application (for nematodes): After area to be treated has been irrigated to field capacity, apply by shank injection to areas where roots are present. Use a sufficient number of injectors to cover area to be treated. If shank application is applied at the root zone, minimal irrigation is required to assure that product covers root zone.

Chemigation application (for nematodes and root rot): Apply Quillaja Extract through the following types of systems. Do not apply this product through any other type of irrigation system.

- Low volume (ground or underground) drip, drip tape, strip tubing, micro-jet sprinklers, mini-sprinklers;
- Sprinkler including center pivot, lateral move, end tow, side (wheel) roll, solid set, or hand move;
- Furrow.

Check irrigation system and emitters to ensure all systems are operating normally before injecting Quillaja Extract. Lack of effectiveness or crop injury can result from non-uniform distribution of treated water.

If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers, chemigation experts or the Distributor of this product.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place. In addition, check local and state regulations regarding pesticide injection into public water systems.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Maintain the system's operating pressure low enough to prevent fogging and/or misting during applications. Inject Quillaja Extract into the irrigation system after the filter(s) or shut off the automatic back flush system in order to avoid back flushing of treated water.

Systems using a gravity flow pesticide dispensing system must meter the product into the water at the head of the field and downstream of the hydraulic discontinuity, such as

a drop structure or weir box, to decrease potential for water source contamination from backflow if water flow stops.

Systems using a pressurized water and pesticide injection system must meet the following requirements:

- The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
- The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of material that are compatible with pesticide and capable of being fitted with a system interlock.

It is highly recommended that the soil be irrigated to field capacity (down to two feet of soil) before pesticide application. For best results, inject Quillaja Extract into the irrigation line in the last quarter of the irrigation time. Continue irrigation until all lines are flushed. Maintain irrigation for enough time to assure this product has penetrated down into the targeted root zone. Do not over irrigate after applying this product. If excessive watering occurs immediately following application, this product may move down past the desired root zone due to its high water solubility. Do not irrigate for at least 24 hours following application of this product. Pest injury to the crop or lack of effectiveness in growth response may result from uneven distribution of this product during application.

Do not allow air in the line prior to injecting Quillaja Extract. The product's density will cause swelling of the line due to foam formation and prevent uptake of material. If a pesticide supply tank is used, follow directions listed under "Mixing" above. There generally will be some level of foam at the base of the wetted area until it dissolves (usually within 30 minutes after application, depending on temperature and amount of water following application).

If applied in heavy rainfall areas, avoid application during rain or when rain is forecasted within the next 24 hours that may exceed movement of this product past targeted root zone.

Do not apply when wind speed favors drift beyond the areas intended for treatment

Application Rates for Control of Nematodes

To control/suppress plant parasitic nematodes, apply Quillaja Extract to the full irrigated zone. For row crops, the irrigated zone is 30-50% of the row area. For orchards or around trees, apply from tree trunk to drip-line to cover at least 50% of soil area or the area under the canopy of the tree, whichever is greatest. Single applications should be made in the spring just prior to or during root flush, and again in the fall after harvest. For best results, multiple applications may be made in the spring, followed by a single application in the fall after harvest.

Crop	Remarks
Berries: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Huckleberry, Loganberry, Raspberry (black and red)	On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.
Citrus: Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo	On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.
Grapes (raisin, table, wine)	For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.
Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)	
Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince	
Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune	

Cole Crops:

Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables:

Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables:

Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables:

Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Strawberry

Apply 1-7 days preplant to the planting zone. Apply centered on the top of the row on pre-wetted soil. Follow with water to assure penetration of the product into the root zone.

On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.

On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.

For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.

<p>Bulb Vegetable: Garlic, Leek, Onion (including dry bulb, green and Welch), Shallot</p> <p>Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Ginseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)</p> <p>Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals</p>	<p>Apply prior to planting to row area to be planted. Apply centered on the top of the row on pre-wetted soil. Follow with water to assure penetration of the product into the root zone.</p> <p>On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.</p>
<p>Turfgrass Ornamental lawns, Golf courses, Sod farms</p> <p>For control of <i>Anguina pacifica</i> nematode only.</p>	<p>Apply 9 fl.oz. in 3-7 gallons water per 1,000 sq.ft. (equivalent to 3 gallons in 130-300 gallons water per acre) using a sprayer with a pressure nozzle tip applicator sufficient to penetrate into the lower part of the turf leaves where <i>Anguina pacifica</i> nematode galls are formed. Do not exceed a concentration of 1.5% solution of Quillaja Extract in any application.</p> <p>Repeat applications every 5-10 days. Additional applications to break the life cycle of the nematode should be repeated 2-4 times within 60 days to significantly reduce this pest problem in one season.</p> <p>Do not water turfgrass for at least 12 hours following application of Quillaja Extract. Quillaja Extract is water soluble and does not require additional water application through sprinkler following application.</p>

Application Rates for Control of Fungi

For control/suppression of **POWDERY MILDEW** in the following field and greenhouse-grown crops, apply 1-4 pints Quillaja Extract per acre as a foliar spray in 50-100 gallons

Desert King – Quillaja Extract: EPA Reg. No. 82572-1
Label Version (8); September 28, 2009
Page 9 of 19

water per acre (equivalent to 0.5-1.5 fl.oz. in 1-2 gallons water per 1,000 sq.ft.) every 7-10 days depending on severity of infection. A surfactant is not necessary, but the addition of a wetting agent, such as Yucca Ag-Aide™, may increase efficacy. Quillaja Extract may be tank mixed with Sterol Inhibitor type fungicides.

Berries and Small Fruits: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Grape (raisin, table, wine), Huckleberry, Kiwifruit, Loganberry, Raspberry (black and red), Strawberry

Bulb Vegetable: Garlic, Leek, Onion (including dry bulb, green and Welsh), Shallot

Cereal Grains: Barley, Buckwheat, Corn, Millet, (pearl and proso), Oats, Popcorn, Rice, Rye, Sorghum (milo), Teosinte, Triticale, Wheat, Wild rice

Cole Crops: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables: Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Legume Vegetables (succulent or dried): Bean (*Lupinus*, *Phaseolus* and *Vigna* spp.), Broad bean, Chickpea, Guar, Jackbean, Lablab bean, Lentil, Pea (*Pisum* spp.), Pigeon pea, Soybean, Sword bean

Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)

Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince

Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Gingseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune

Subtropical Fruits: Banana, Date, Mango, Papaya, Pineapple

Additional crops: Hops, Mint (peppermint, spearmint), Tobacco

Herbs and Spices: Allspice, Angelica, Anise, Annatto, Balm, Basil, Borage, Burnet, Camomile, Caper buds, Caraway, Cardamom, Cassia, Catnip, Celery seed, Chervil, Chive, Cinnamon, Clary, Clove buds, Coriander, Coriander,

Costmary, Culantro, Cumin, Curry, Dill, Fennel, Fenugreek, Grains of paradise, Horehound, Hyssop, Juniper berry, Lavender, Lemongrass, Lovage, Mace, Marigold, Marjoram, Mustard, Nasturtium, Nutmeg, Parsley, Pennyroyal, Pepper, Poppy seed, Rosemary, Rue, Saffron, Sage, Savory, Sweet bay, Tansy, Tarragon, Thyme, Vanilla, Wintergreen, Woodruff, Wormwood

Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals

Turf: Ornamental lawns, golf courses and sod farms

For control/suppression of **PHYTOPHTHORA** and **PYTHIUM ROOT ROT** in the following field and greenhouse-grown crops, apply 2-4 quarts Quillaja Extract in 200 gallons water per acre (equivalent to 1.5-3 fl.oz. in 5 gallons water per 1,000 sq.ft.) to achieve a concentration of 2,500-5,000 ppm. Apply in early spring and fall, prior to root flush when soil temperatures are optimum for root infection. Apply to the entire root zone following, or at the end of, an irrigation cycle For best results, repeat application every 7 days, for up to 6 weeks. A surfactant is not necessary, but the addition of a wetting agent, such as Yucca Ag-Aide™, may increase efficacy. Quillaja Extract may be tank mixed with Sterol Inhibitor type fungicides.

Berries and Small Fruits: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Grape (raisin, table, wine), Huckleberry, Kiwifruit, Loganberry, Raspberry (black and red), Strawberry

Citrus: Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo,

Cole Crops: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables: Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)

Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince

Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Gingseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune

Additional crops: Avocado, Kiwifruit

Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals

Application Rates to Enhance Plant Growth and Yield

Under good growing conditions, absent of plant parasitic nematodes or plant parasitic fungi, Quillaja Extract is beneficial to plant growth and yield as described below.

Crop	Benefit	Rate per Acre	Comment
Grapes	Increased Fruit Yield and Root Development	1-2 quarts	Apply at root flush followed by 2-4 applications at 7-14 day intervals.
Citrus	Increased Root Development	1-2 gallons	Apply at root flush followed by 2 quarts/acre every 14 days for 4-6 weeks.
Strawberry	Increased Root Development	2-4 pts	Apply every 14 days for 8-10 weeks.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in cool dry area.

Pesticide Disposal: Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Un-Refillable Container. Do not refill or reuse this container. Triple rinse (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Quillaja Extract

A Bio-Pesticide

*For Control of Plant Parasitic Nematodes and Home Orchards &
Vineyards, Vegetable Gardens, Lawns and Ornamentals*

Active Ingredient:

*Saponins of Quillaja saponaria 8.60%

Other Ingredients 91.40%

Total 100.00%

*bidesmosidic derivatives of quillajic acid substituted with a trisaccharide at C-3 and an oligosaccharide in C-28

KEEP OUT OF REACH OF CHILDREN

WARNING - ADVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

Manufactured for:
Lawn and Garden Products, Inc.
P.O. Box 35000
Fresno, CA 93745
(559) 499-2100
www.montereylawngarden.com

EPA Reg. No.: 82572-1
EPA Est. No.: XXXXX-XX-XX

Net Contents: XX Gallons
Batch Code: XXX

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye damage. Do not get in eyes or on clothing. Harmful if swallowed or absorbed through skin. Avoid contact with skin. Applicators should wear long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material and shoes plus socks. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Never apply material so as to contaminate eating or drinking area. Remove contaminated clothing and wash before reuse. Keep unprotected persons out of treated areas until sprays have dried.

ENVIRONMENTAL HAZARDS

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL BEFORE EACH USE.

For residential use in home orchards & vineyards, vegetable gardens, lawns and ornamentals.

APPLICATION METHODS

After area to be treated has been irrigated, apply with a band or broadcast type sprayer. After application has been made it may be necessary to water with either drip, above ground sprinklers or reduced amount of furrow irrigation. Do not over irrigate following application of this product. Do not use flood irrigation to apply this product into the ground. Over irrigation will move the desired concentration of the product too quickly past the targeted root zone.

For application in home orchards and around trees, begin application next to the tree trunk and spray at least 50% of soil area or the area under the canopy of the tree, whichever is greatest.

Apply solution within three hours of mixing.

If applied in heavy rainfall areas, avoid application during rain or when rain is forecasted within the next 24 hours that may exceed movement of this product past targeted root zone.

Do not apply when wind speed favors drift beyond the areas intended for treatment.

Application Rates for Control of Nematodes

To control/suppress plant parasitic nematodes, apply Quillaja Extract to the full irrigated area. For home orchards or around trees, apply from tree trunk to drip-line to cover at

least 50% of soil area or the area under the canopy of the tree, whichever is greatest. Single applications should be made in the spring just prior to or during root flush, and again in the fall after harvest. For best results, multiple applications may be made in the spring every 7 to 14 days for up to 10 weeks, followed by a single application in the fall after harvest.

Use Site	Rate
Berries (Not for use in California): Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Huckleberry, Loganberry, Raspberry (black and red)	Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.
Citrus: Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo	Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.
Grapes	Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.
Nut Trees: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)	Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.
Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince	Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.
Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune	Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.
Cole Crops: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizune, Mustard greens, Mustard spinach, Rape greens	Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.
Cucurbit Vegetables: Chaoyote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, Crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including	Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.

<p>crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)</p> <p>Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato</p> <p>Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard</p> <p>Strawberry</p> <p>Bulb Vegetables: Garlic, Leek, Onion (including dry bulb, green and Welch), Shallot</p> <p>Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Ginseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)</p> <p>Ornamentals: Bare root, container, bedding and flowering plants, landscape, potted flowering, shade and flowering trees, woody ornamentals</p>	<p>Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.</p> <p>Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.</p> <p>Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.</p> <p>Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.</p> <p>Apply 8 fl. oz. in 6 gallons of water per 1,000 sq. ft.</p>
<p>Lawns: For control of <i>Anguina pacifica</i> nematode only.</p>	<p>Apply 9 fl. oz. in 3-7 gallons of water per 1,000 sq. ft. using a sprayer with a pressure nozzle tip applicator sufficient to penetrate into the lower part of the turf leaves where <i>Anguina pacifica</i> nematode galls are formed. Do not exceed a concentration of 1.5% Quillaja Extract in any application.</p> <p>Repeat applications every 5-10 days.</p>

	<p>Additional applications to break the life cycle of the nematode should be repeated 2-4 times within 60 days to significantly reduce this pest problem in one season.</p> <p>Do not water lawn for at least 12 hours following application of Quillaja Extract. Quillaja Extract is water soluble and does not require additional water application through sprinkler following application.</p>
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Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: To be stored in original container in a cool, well-ventilated areas inaccessible to children and pets. Store above 40°F.

Pesticide/Container Disposal: **If empty:** Nonrefillable container. Do not refill or reuse this container. Place in trash or offer for recycling in available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY

Desert King Chile warrants that this product conforms to the chemical description on the label and is reasonable fit for the purposes set forth in the Complete Directions for Use label booklet ("Directions") when used in accordance with those Directions under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

[] indicates optional text

Optional Label Claims:

- Controls and/or Suppresses certain foliar diseases such as Powdery Mildew(s)
- Suppresses [Nematodes], [Powdery Mildew]
- For use also on Vegetable Crops Such as: Carrots, Peppers, Tomatoes, Broccoli, Squash, and Beets.

MATERIAL TO BE ADDED TO JACKET

REG #: 82572-1

Description: deficiency letter

if applicable, check all that are attached:		Send to CSC
<input type="checkbox"/>	new stamped accepted label	
<input type="checkbox"/>	new CSF	
<input type="checkbox"/>	notification	
<input checked="" type="checkbox"/>	other: deficiency letter, other correspondence	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer: John Fournier Date: 11/25/2009

Phone: (703) 308-0169 Division: BPPD



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FILE COPY

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OCT 28 2009

Heather R. Bjornson, Regulatory Agent
Technology Sciences Group, Inc.
1150 18th Street, N.W. Ste. 1000
Washington, DC 20036

Subject: Quillaja Extract
EPA Registration No. 82572-1
Data Submitted as a Condition of Registration
Application Dated January 15, 2009
Decision # 406151

Dear Ms. Bjornson:

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the application referred to above, submitted in connection with registration under FIFRA section 3(c)(5). BPPD has concluded that the efficacy data submitted in response to the conditions of registration are **not** acceptable, and that the following deficiencies **must** be addressed before we can proceed with the review of your submission and issue the registration for this product.

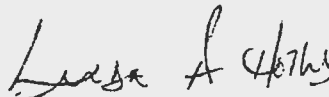
BPPD CONCLUSIONS

1. Biochemical Pesticides Branch has identified the following deficiencies in the efficacy data:
 - a. The tested products are not properly identified as requested by OPPTS Guideline 810.1000. The registered name of the tested product is Quillaja Extract, but the unregistered names QLAGri, and QLAGri35 are used in the studies together with the distributor's name Nema-Q. The trademarks EF500 and Nemacur are also used in comparative tests. You must use the currently registered name in all the studies or submit an application to amend your registration to include QLAGri, QLAGri35, and Nema-Q on the product label as alternative brand names of EPA Reg. No. 82572-1. You must also provide additional information identifying EF500 and Nemacur, including their EPA registration numbers and producers.

- b. There is a discrepancy between the percentage of the active ingredient in the most current CSF (7.5%) and the ingredient statement on the label (8.6%). You must submit an application to amend your CSF to include the correct percentage of active ingredient.
- c. The comparison between the effects of Quillaja Extract and the other trademark nematocides is often omitted in the conclusions.
- d. The product CropGuard (EPA Reg. No. 7655-1), containing 85% Silicon Dioxide from Diatomaceous Earth, is used in some studies as a positive control but is not registered as a nematocide.
- e. Please prepare a brief summary explaining which label claims for Quillaja Extract are supported by the results of the submitted efficacy studies.
- f. The statistical differences are reported and graphed based on transformed values, $\log_{10}(x+1)$. Graphs should be constructed using the original values to better illustrate study results.
- g. In order for the product to be effectively used for maintaining manageable pest population levels when used in IPM programs, it is important to assess whether this product is effective in keeping the pest population below economic injury levels, established from 12,000 to 18,000 larvae per 500 cc soil or 1,100 to 1,400 females per gram of root.
- h. For practical agricultural purposes, it is important to assess the relationship between product performance on the pest and its indirect effect on yield enhancement.

By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. You will have 75 days from the date of this letter to submit the required information before the Agency will withdraw your application because it is incomplete. If you have any questions please contact John Fournier at 703-308-0169, or by email at fournier.john@epa.gov.

Sincerely,



Linda A. Hollis, Chief,
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)



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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Desert King Chile, Ltd. Antonio Bellet 77 Of. 401, Providencia, Santiago, Chile Tel. 800 982 2235	EPA Registration Number/File Symbol 82572-1
Active Ingredient(s) and/or representative test compound(s) Quillaja saponins	Date January 15, 2009
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial: Food crop, Nonfood	Product Name Quillaja Extract

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date Jan. 15, 2009	Typed or Printed Name and Title Heather R. Bjornson, Regulatory Agent
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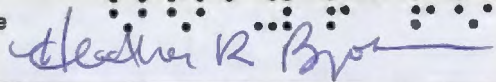


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DATA MATRIX

Date January 15, 2009			EPA Reg. No./File Symbol 82572-1		Page 1 of 7
Applicant's/Registrant Name and Address Desert King Chile Antonio Bellet 77 Of . 401 Providencia, Santiago, Chile			Product Quillaja Extract		
Ingredient Quillaja saponins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.1550	Product Identity and Composition	46568401 46972501	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.1600	Description of Materials Used to Manufacture Product	46568401 46972501	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.1600	Description of Production Process	46568401 46972501	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.1620	Description of the Formulation Process	46568401 46972501 47542301	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.1670	Discussion of the Formation of Impurities	46568401 46972501	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.1750	Certified Limits	46568401 46972501	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.1800	Enforcement Analytical Method	46568401 46972501	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.6302	Color	46568402 46972502	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.6303	Physical State	46568402	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.6304	Odor	46568402 46972504	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.6313	Stability to normal and elevated temperatures, metals and metal ions-TGA	46568402 46972502	Desert King Chile	OWN	6/7/2005 submission
Signature 			Name and Title Heather R. Bjornson, Regulatory Agent		Date January 15, 2009

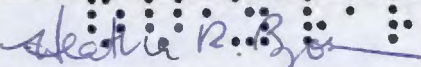


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Applicant's/Registrant Name and Address Desert King Chile Antonio Bellet 77 Of . 401 Providencia, Santiago, Chile		Product Quillaja Extract			
Ingredient Quillaja saponins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.7000	pH	46568402	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.7100	Viscosity	46568402	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.7200	Melting Point/ melting range - PAI	46568402	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.7220	Boiling Point/boiling range - PAI	46568402 46972502	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.7300	Density, Bulk Density, Specific Gravity	46568402	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.6314	Oxidation/Reduction	46568402	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.6315	Flammability	46568402	Desert King Chile	OWN	6/7/2005 submission
Signature 	Name and Title Heather R. Bjornson, Regulatory Agent			Date January 15, 2009	



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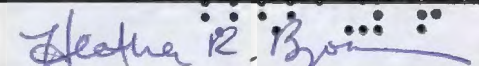
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Applicant's/Registrant Name and Address Desert King Chile Antonio Bellet 77 Of . 401 Providencia, Santiago, Chile	Product Quillaja Extract	

Ingredient Quillaja saponins

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.6317	Storage Stability	46568402	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.6319	Miscibility	46568402	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.6320	Corrosion Characteristics	46568402	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.7750	Partition coefficient	46568402	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.7840, 830. 7860	Water solubility	46568402	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.7950	Vapor Pressure	46568402	Desert King Chile	OWN	6/7/2005 submission
OPPTS 830.7050	UV Absorption	46972503	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 830.7560	Partition Coefficient, Kow	46972503	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 830.7950	Volatility	46972503	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 835.1210	Soil thin layer chromatography		Desert King Chile	OWN	WAIVER REQUEST
OPPTS 835.1220	Sediment and soil adsorption / desorption	46972503	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 835.2110	Hydrolysis as a function of pH	46972503	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 835.2210	Direct photolysis rate in water by sunlight	46972503	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 835.3100	Aerobic aquatic biodegradation	46972503	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 835.3300	Soil biodegradation	46972503	Desert King Chile	OWN	WAIVER REQUEST
			Name and Title Heather R. Bjornson, Regulatory Agent		Date January 15, 2009

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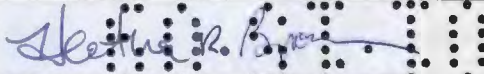
Date January 15, 2009			EPA Reg. No./File Symbol 82572-1		Page 4 of 7
Applicant's/Registrant Name and Address Desert King Chile Antonio Bellet 77 Of. 401 Providencia, Santiago, Chile			Product Quillaja Extract		
Ingredient Quillaja saponins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 850.1400	Fish Life Cycle Toxicity	46972503	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 870.1100	Acute Oral Toxicity	46608101	Desert King Chile	OWN	6/7/2005 submission
OPPTS 870.1200	Acute Dermal Toxicity	46608102	Desert King Chile	OWN	6/7/2005 submission
OPPTS 870.1300	Acute Inhalation Toxicity	46774901	Desert King Chile	OWN	6/7/2005 submission
OPPTS 870.2400	Primary Eye Irritation	46608103 47542302 47542303	Desert King Chile	OWN	6/7/2005 submission
OPPTS 870.2500	Primary Dermal Irritation	46608104	Desert King Chile	OWN	6/7/2005 submission
OPPTS 870.2600	Dermal Sensitization	46608105 46741302	Desert King Chile	OWN	6/7/2005 submission
OPPTS 870.3100	Subchronic Dietary Toxicity	46608106	Desert King Chile	PL	6/7/2005 submission
OPPTS 870.3250	90-Day Dermal Toxicity	46608110	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 870.3465	90-Day Inhalation Toxicity	46608110	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 870.3700	Teratogenicity	46608110	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 870.4100	Chronic Dietary Toxicity	46608107	Desert King Chile	PL	6/7/2005 submission
OPPTS 870.4300	Chronic Toxicity/Carcinogenicity	46608108	Desert King Chile	PL	6/7/2005 submission
OPPTS 870.5000	Genotoxicity	46608110	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 850.1010	Aquatic Invertebrate Toxicity	46608110	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 850.1075	Acute Toxicity of Freshwater Fish (Carp)	46608109	Desert King Chile	OWN	6/7/2005 submission
Signature <i>Heather R. Bjornson</i>			Name and Title Heather R. Bjornson, Regulatory Agent		January 15, 2009



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Applicant's/Registrant Name and Address Desert King Chile Antonio Bellet 77 Of. 401 Providencia, Santiago, Chile			Product Quillaja Extract		
Ingredient Quillaja saponins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 850.2100	Avian Oral Toxicity	46568412	Desert King Chile	OWN	6/7/2005 submission
OPPTS 850.2200	Avian Dietary Toxicity	46608110	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 850.4100	Non-Target Plant Testing	46608110	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 880.3550	Immunotoxicity	46608110	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 880.4350	Non-Target Insect Testing	46608110	Desert King Chile	OWN	WAIVER REQUEST
OPPTS 810.2700	Efficacy of Quillaja Extract on White Rice	46608111	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Efficacy of Quillaja Extract on Cabernet Sauvignon Grape Plants III	46608112	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Efficacy of Quillaja Extract on Chardonnay Grape Plants III	46608113	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Efficacy of Quillaja Extract on Cabernet Sauvignon Grape Plants I	46608114	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Efficacy of Quillaja Extract on Butternut Squash Plants II	46608115	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Efficacy of Quillaja Extract on Butternut Squash Plants	46608116	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Efficacy of Quillaja Extract on Zucchini Plants	46608117	Desert King Chile	OWN	6/7/2005 submission
Signature 			Name and Title Heather R. Bjornson, Regulatory Agent		Date January 15, 2009



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Date January 15, 2009	EPA Reg. No./File Symbol 82572-1	Page 6 of 7
Applicant's/Registrant Name and Address Desert King Chile Antonio Bellet 77 Of . 401 Providencia, Santiago, Chile	Product Quillaja Extract	

Ingredient Quillaja saponins

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 810.2700	Efficacy of Quillaja Extract on Carrot Plants	46608118 46972510	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Efficacy of Quillaja Extract on Cabernet Sauvignon Grape Plants II	46608119 46972509	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Efficacy of Quillaja Extract on Walnut Crops	46608120 46972506	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Efficacy of Quillaja Extract on Tomato Plants	46608121	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Efficacy of Quillaja Extract on Tomato Plants II	46608122 46972507	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Efficacy of Quillaja Extract on Lilly Bulb Plants	46631001	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Efficacy of Quillaja Extract on Butternut Squash Plants III	46608124	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Efficacy of Quillaja Extract on the Root-Knot Nematode	46972504	Desert King Chile	OWN	6/7/2005 submission
OPPTS 810.2700	Control of Plant Parasitic Nematodes with Quillaja Extract	46972505	Desert King Chile	PL	6/7/2005 submission
OPPTS 810.2700	Efficacy of QE on Valencia Orange Trees	This submission	Desert King Chile	OWN	
OPPTS 810.2700	Efficacy of QE on Minneola Tangelo	This submission	Desert King Chile	OWN	
OPPTS 810.2700	Efficacy of QE on Crimson Grapes	This submission	Desert King Chile	OWN	

Signature 	Name and Title Heather R. Bjornson, Regulatory Agent	Date January 15, 2009
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Date January 15, 2009	EPA Reg. No./File Symbol 82572-1	Page 7 of 7
Applicant's/Registrant Name and Address Desert King Chile Antonio Bellet 77 Of . 401 Providencia, Santiago, Chile	Product Quillaja Extract	

Ingredient Quillaja saponins

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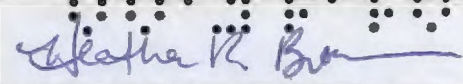
Signature		Name and Title Heather R. Bjornson, Regulatory Agent	Date January 15, 2009
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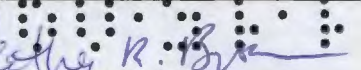
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Applicant's/Registrant Name and Address Desert King Chile Antonio Bellet 77 Of . 401 Providencia, Santiago, Chile			Product Quillaja Extract		
Ingredient Quillaja saponins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Desert King Chile	OWN	6/7/2005 submission
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Signature 			Name and Title Heather R. Bjornson, Regulatory Agent		Date January 15, 2009



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Ingredient Quillaja saponins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Desert King Chile	OWN	6/7/2005 submission
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			Desert King Chile	OWN	6/7/2005 submission
Signature 			Name and Title Heather R. Bjornson, Regulatory Agent		Date January 15, 2009



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Ingredient Quillaja saponins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
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			Name and Title Heather R. Bjornson, Regulatory Agent	Date January 15, 2009	



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Date January 15, 2009	EPA Reg. No./File Symbol 82572-1	Page 4 of 7
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Product
Quillaja Extract

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Desert King Chile	OWN	WAIVER REQUEST
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	PL	6/7/2005 submission
			Desert King Chile	OWN	WAIVER REQUEST
			Desert King Chile	OWN	WAIVER REQUEST
			Desert King Chile	OWN	WAIVER REQUEST
			Desert King Chile	PL	6/7/2005 submission
			Desert King Chile	PL	6/7/2005 submission
			Desert King Chile	OWN	WAIVER REQUEST
			Desert King Chile	OWN	WAIVER REQUEST
			Desert King Chile	OWN	6/7/2005 submission

Name and Title
Heather R. Bjornson, Regulatory Agent

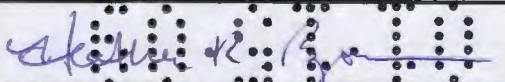
January 15, 2009



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date January 15, 2009			EPA Reg. No./File Symbol 82572-1		Page 5 of 7
Applicant's/Registrant Name and Address Desert King Chile Antonio Bellet 77 Of . 401 Providencia, Santiago, Chile			Product Quillaja Extract		
Ingredient Quillaja saponins					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	WAIVER REQUEST
			Desert King Chile	OWN	WAIVER REQUEST
			Desert King Chile	OWN	WAIVER REQUEST
			Desert King Chile	OWN	WAIVER REQUEST
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
Signature 			Name and Title Heather R. Bjornson, Regulatory Agent		Date January 15, 2009



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
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DATA MATRIX

Date January 15, 2009	EPA Reg. No./File Symbol 82572-1	Page 6 of 7
Applicant's/Registrant Name and Address Desert King Chile Antonio Bellet 77 Of . 401 Providencia, Santiago, Chile	Product Quillaja Extract	

Ingredient	Quillaja saponins
-------------------	--------------------------

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	OWN	6/7/2005 submission
			Desert King Chile	PL	6/7/2005 submission
			Desert King Chile	OWN	
			Desert King Chile	OWN	
			Desert King Chile	OWN	

Signature

Heather R. Brown

Name and Title

Heather R. Bjornson, Regulatory Agent

Date _____

January 15, 2009



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date January 15, 2009	EPA Reg. No./File Symbol 82572-1	Page 7 of 7
Applicant's/Registrant Name and Address Desert King Chile Antonio Bellet 77 Of . 401 Providencia, Santiago, Chile	Product Quillaja Extract	

Ingredient	Quillaja saponins
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[illegible]

Signature 	Name and Title Heather R. Bjornson, Regulatory Agent	Date January 15, 2009
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JUL 12 2007

808522 / B59
1170MEMORANDUM

SUBJECT: Consideration of a conditional registration of the active ingredient Saponins of *Quillaja saponaria* (PC Code 097095, EPA Registration Number 82572-R). This compound will be incorporated into end-use products intended to control plant parasitic nematodes and fungi in vineyards, fields of ornamental plants and food crops.

----- **DECISION MEMORANDUM** -----

FROM: W. Michael McDavit, Associate Director
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs

TO: Debra Edwards, Ph. D., Director
Office of Pesticide Programs

ISSUE

Should the Agency grant a conditional registration under FIFRA § 3(c)(7)(B) for the new biochemical active ingredient, Saponins of *Quillaja saponaria* (PC Code 097095 EPA Registration Number 82572-R) to be used in end-use products intended for agricultural applications for the control of fungi and nematodes in vineyards, field crops and ornamentals?

APPLICANT INFORMATION

On August 26, 2005, the Agency received an application filed by Desert King Chile, Ltd., Antonio Bellet 77 OF.401, Providencia, Santiago, Chile 6640209 (submitted by Technology Sciences Group, Inc., 1101 17th Street, NW, Suite 500, Washington, DC 20026 to register the product Quillaja Extract containing 8.60% of the new biochemical active ingredient, Saponins of *Quillaja saponaria* (PC Code 097095). A notice of receipt of this application was published in the Federal Register April 5, 2006 (71 FR 17095).

CONCURRENCES

SYMBOL	7511P	7511P	7511P					
SURNAME	Bennhard	J. Hany	COLE					
DATE	6/21/07	7/11/07	7/11/07					

BACKGROUND AND CONCLUSIONS

The Biopesticides and Pollution Prevention Division (BPPD) reviewed available and submitted data and information regarding the proposed use of the saponins of *Quillaja saponaria*. Evaluations of the data and conclusions are summarized and discussed in the attached Biopesticide Registration Action Document (BRAD). The technical grade active ingredient (TGAI) is a water extract from the bark of *Quillaja saponaria*. These extracts commonly known as Saponins, are naturally occurring glycosides in tree bark and wood and form soap-like foams in aqueous solution.

BPPD has considered the saponins of *Quillaja saponaria* in light of relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and determined there will be no unreasonable adverse effects from the use of this product. BPPD has considered available data on these Saponins, including the natural occurrence, their common use as food items as emulsifiers in baked goods, candies, frozen dairy products, gelatin, and puddings, and the lack of reported adverse effects. BPPD believes that end use products containing the saponins of *Quillaja saponaria*, can be used without causing unreasonable adverse effects to humans or the environment. BPPD has concluded that this registration should be issued on a conditional basis pending submission of acceptable product performance data.

The data submitted by applicant and reviewed by BPPD support the application to register the product Quillaja Extract containing 8.60% of the new biochemical active ingredient, Saponins of *Quillaja saponaria*, when applied / used as directed on the label and in accordance with good agricultural practices.

OFFICE DIRECTOR CONCURRENCE

Based on the discussion above and the summarized data evaluations in the attached BRAD, BPPD recommends that the product Quillaja Extract containing 8.60% of the new biochemical active ingredient Saponins of *Quillaja saponaria* (PC Code 097095), be conditionally registered under 3(c)(7)(B) of FIFRA for use to control fungi and nematodes in vineyards, field crops and ornamentals.

Concurrence: _____

Non Concurrence: _____

Date: _____



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 11 2007

Heather R. Bjornson
Regulatory Consultant for Desert King Chile, Ltd
Technology Sciences Group, Inc.
1150 18th Street NW, Suite 1000
Washington, DC 20036

Dear Ms. Bjornson:

RE: Desert King Chile Ltd, Quillaja Extract, EPA Reg. No. 82572-R
Pesticide Product Registration Pre-Acceptance Letter

This is a pre-acceptance letter regarding Desert King Chile Ltd's application to register the above referenced product for a Section 3 registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Environmental Protection Agency (EPA) will consider registering Desert King Chile Ltd's product under FIFRA Section 3(c)(7)(A) provided Desert King Chile Ltd Agree to the conditions as defined in this letter.

To enable the Agency to continue to process the subject registration application, EPA requests that Desert King Chile Ltd agree in writing to the following:

1. Desert King Chile Ltd will submit product performance data within one year from the date registration is granted for the product;
2. Desert King Chile Ltd will be required to meet with the appropriate Biochemical Pesticides Branch (BPB) representatives to determine the specific product performance data to be conducted and submitted;
3. Desert King Chile Ltd will be responsible for initiating the meeting referenced above under condition (2) and this meeting shall commence soon after product registration is granted, not to exceed 2 months post registration.

This letter does not constitute a commitment to register the subject product, nor is it intended to imply that EPA will register the subject product. Rather, the purpose of this letter is to inform you that, if Desert King Chile Ltd agrees to the conditions in writing as

described in this letter, EPA will be able to continue to process the registration application in accordance with our normal procedures.

Sincerely,

Linda A. Hollis

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
(7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number:
82572-1

Date of Issuance:

JUL 14 2007

Term of Issuance: **Conditional**

Name of Pesticide Product:
Quillaja Extract

NOTICE OF PESTICIDE:

☒ **Registration**
☐ **Reregistration**
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Heather R. Bjornson
Regulatory Consultant for Desert King Chile, Ltd.
Technology Sciences Group, Inc.
1150 18th Street NW, Suite 1000
Washington, DC 20036

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Sec. 3(c)(7)(A) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit the following data on or before July 30, 2008:
Acceptable efficacy data that supports the claims for the control of nematodes on the representative group of crops and/or turf as to be determined in the meeting between BPPD and Desert King Chile Ltd. two (2) months post registration.
3. Submit three (3) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description and final printed labeling.

Signature of Approving Official:

W. Michael McDavit

Date:

7/14/07

CONCURRENCES

SYMBOL

SURNAME *W. Michael McDavit*, Associate Director,
DATE *Biopesticides and Pollution Prevention Division*

This product is conditionally registered under FIFRA Sec. 3(c)(7)(B) because the Agency has imposed the data requirements listed under item 2, above.

The expiration date for this conditionally registered product is July 30, 2008.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Michael McDavit", followed by a stylized flourish.

W. Michael McDavit
Associate Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures

Receipt for Section 3

S: Resubmission: ☐ Yes ☒ No

Regulatory Type: Fee For Service: ☐ Yes ☒ No

Application Type: Billable: ☐ Yes ☒ No

Company:

Risk Manager:

Product#: Product Name:

Override#:

Me Too Me Too

Section3: Product Name:

Application Date: OPP Rec'd Date:

Front End Date: Risk Manager Send Date:

FFS Due Date:

OPP Target Date:

Negotiated Due Date:

Fast Track: ☐

Receipt Description:

Signature Date:

Form: ☐

New Ingredient:

Request Date:

New Ingredient:

Request Date:

Signature Date:

Receipt Content:

575 John

(efficacy data in response to conditional reg)

For Nina's Review

LH
2/17/09

AIO-John
FEB 18 2009
sdh

476452-00



WASHINGTON

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Linda Hollis

Biopesticide and Pollution Prevention Division

Office of Pesticide Programs

Environmental Protection Agency

Room S-4900, One Potomac Yard

2777 South Crystal Drive

Arlington, VA 22202-4501

January 15, 2009

RE: Quillaja Extract (EPA Reg. No. 82572-1)

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

Submission of efficacy data as a condition of registration

Dear Ms. Hollis:

Technology Sciences Group, on behalf of Desert King Chile, is submitting the enclosed efficacy studies to support the product registration of Quillaja Extract. You will find the following enclosed:

- 1) Amendment application form,
- 2) Certification with respect to data citation,
- 3) Data matrices (confidential and non-confidential versions),
- 4) Transmittal document, and
- 5) Data volumes 2-13 (refer to the transmittal document for study title and other information).

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

Please do not hesitate to contact me directly with any questions and/or concerns.

Sincerely,

Heather R. Bjornson

Regulatory Agent for Desert King Chile/Desert King International

VOLUME 1 OF 13 SUBMISSION

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Desert King Chile, Ltd.
Antonio Bellet 77 Of. 401
Providencia, Santiago, Chile

REGULATORY ACTION:

Submission of efficacy data to support Quillaja Extract; EPA Reg. No. 82572-1.

TRANSMITTAL DATE:

January 15, 2009

LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
	1 of 13	(Transmittal Document)	-----
47645201	2 of 13	Efficacy of <i>Quillaja Extract</i> on Valencia Orange Trees – Trial One	810.2700
47645202	3 of 13	Efficacy of <i>Quillaja Extract</i> on Valencia Orange Trees – Trial Two	810.2700
47645203	4 of 13	Efficacy of <i>Quillaja Extract</i> on Valencia Orange Trees – Trial Three	810.2700
47645204	5 of 13	Efficacy of <i>Quillaja Extract</i> on Valencia Orange Trees – Trial Four	810.2700
Duplicate of vol 4	6 of 13	Efficacy of <i>Quillaja Extract</i> on Valencia Orange Trees – Trial Three	810.2700
47645205	6 of 13	Efficacy of <i>Quillaja Extract</i> on Minneola Tangelo	810.2700
47645206	7 of 13	Efficacy of <i>Quillaja Extract</i> on Chrimson Grape – Trial One	810.2700
47645207	8 of 13	Efficacy of <i>Quillaja Extract</i> on Chrimson Grape – Trial Two	810.2700
47645208	9 of 13	Efficacy of <i>Quillaja Extract</i> on Table GRAPES Page 1 of 2	810.2700

47645209	10 of 13	Efficacy of <i>Quillaja Extract</i> on Grape cv. Flame	810.2700
47645210	11 of 13	Efficacy of <i>Quillaja Extract</i> on the Root Knot Nematode on Cucumber -Alabama 2008	810.2700
47645211	12 of 13	Efficacy of <i>Quillaja Extract</i> on Cucumber And Cucumber Yields	810.2700
47645212	13 of 13	Efficacy of <i>Quillaja Extract</i> on the Root Knot Nematode on Cucumber	810.2700

COMPANY NAME: Desert King Chile, Ltd.

COMPANY OFFICIAL:



Heather R. Bjornson, Regulatory Agent

COMPANY CONTACT:

Heather R. Bjornson, Regulatory Agent
Technology Sciences Group, Inc.
1150 18th Street, N.W. Ste. 1000
Washington, DC 20036
(202) 828-8945



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG - 2 2006

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC SUBSTANCES

CONFIDENTIAL BUSINESS INFORMATION

MEMORANDUM

SUBJECT: Science Review in Support of the Registration of Quillaja Extract Containing Saponins of *Quillaja saponaria* As It's Active Ingredient. Review of Product Chemistry, Tier I Toxicity Studies, Tier I Non-Target Organism Studies, Waiver Requests, Efficacy Studies, an Endangered Species Assessment, and a Request for an Exemption From the Requirements of Tolerances.

EPA File Symbol No.: 82572-R
DP Barcodes: D324679
Decision Nos.: 357857
PC Code: 097095
CAS Nos.: 68990-67-0
MRIDs: 465684-01 & -02; 466081-11 to -22 & -24;
46631001
Tolerance Exemption Petition: PP# 5F7017

FROM: Russell S. Jones, Ph.D., Senior Biologist /s/ 07/28/2006
Biochemical Pesticides Branch
Biopesticide & Pollution Prevention Division (7511C)

TO: Driss Benmhend, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticide & Pollution Prevention Division (7511C)

ACTION REQUESTED

Desert King Chile requests registration of the end-use product Quillaja Extract (EPA File Symbol No. 82572-R) containing the new active ingredient, saponins of *Quillaja saponaria*. The registrant additionally requests an exemption from the requirements of tolerances for the active ingredient. The product is intended for food and non-food use in the control of

nematodes and fungi, and as a plant growth regulator on vineyard, orchard, field, and ornamental crops. In support of the registration and tolerance exemption petition, the registrant has submitted product chemistry studies, Tier I toxicity studies, Tier I non-target organism studies, waiver requests, and efficacy studies.

RECOMMENDATIONS AND CONCLUSIONS

1. The product chemistry submission for the End-use product (EP; EPA File Symbol No. is **Unacceptable**, but upgradable. To upgrade the submission to acceptable, the registrant must:
 - a. In Column 10 of the TGAI CSF: the name of the active ingredient should be stated as "Saponins of *Quillaja saponaria*" containing the following triterpenoid saponins: QS-7, QS 17, QS-18, and QS-21 and their respective percentages in the extract. If chemical names and CAS nos. are available for these four saponins, they must be provided. If available, chemical names (e. g. Quillaic acid 3-O-glucuronide) must be used instead of the QS numbers. The sum of the percentages of all the saponins in the extract will be used to determine the true percentage of active ingredient in the product
 - b. The registrant is directed to refer to the BRAD for Saponins of *Chenopodium quinoa* for guidance in describing the active ingredient;
 - c. Based on the 5-batch analysis of the EP, the percentage by weight of the active ingredient in the product should be **8.6% with upper and lower certified limits of 7.91% and 9.2%**, respectively.
 - d. Remove the other (inert) ingredient [REDACTED] from the formulation. This ingredient is not cleared for food use and must be replaced with a chemically-similar ingredient that is cleared for food use under 40 CFR 180.910, 180.920, and/or List 4A;

NOTE 1:

[REDACTED]

- e. On the CSF: Instead of listing Coextractives, replace with a list (on separate rows) each of the coextracted components as listed in MRID 465684-01 (Table 1., p. 33). Each component must be listed as an inert (other) ingredient with a weight, nominal concentration by percent weight of product, and upper certified limit. Since these coextracted components will be considered manufacturing impurities, no lower certified limit is required.

- f. Provide the actual name and address of the source of the ingredient, water.

NOTE 2: Total weight of product, and some percentages by weight of ingredients were incorrect, but these values may change depending on what ingredient is used to replace [REDACTED].

- g. Since there is no discrete TGAI for the product, the product is considered a TGAI/EP. Therefore, the registrant must present data/information for **color, odor, stability, and boiling point**.
- 2a. Tier I acute oral toxicity, acute dermal toxicity, primary eye irritation, primary dermal irritation, and skin sensitization studies are **Acceptable**; no additional data are required. The EP is in Toxicity Category III for acute oral toxicity and acute dermal toxicity; Toxicity Category II for primary eye irritation; and Toxicity Category IV for primary dermal irritation; the product is not a sensitizer. No acute inhalation study was submitted.
- 2b. The waiver request for **acute inhalation toxicity** is **Unacceptable**, but upgradable. The waiver request is based primarily upon oral toxicity exposure/toxicity data and does not address the inhalation route of exposure and the potential for the product to cause irritation to mucosal membranes and lung tissue. The registrant must conduct an acute inhalation study using the TGAI (or, see Conclusion 2c below);
- 2c. In lieu of an acute inhalation study, the Agency will classify **acute inhalation toxicity in Toxicity Category II** (identical for the Toxicity Category for primary eye irritation) due to its irritation potential. The product label Signal Word, Precautionary Statements, and First Aid Statements must be revised to reflect these Toxicity Categories.
- 2d. the 90-day feeding study is **Unacceptable, but upgradable**. To upgrade the study to acceptable the registrant must submit the method used to prepare the diet formulations, and the storage conditions for the test material and the diet formulations are provided and found to be acceptable.
- 2e. The toxicity information/data submitted by the registrant in support of waivers for the remainder of the Tier I Toxicity data requirements, in conjunction with Agency obtained information, are **Acceptable**; no additional data are required.
- 3a. Tier I Non-target Organism studies/data for avian acute oral toxicity and avian dietary toxicity are **Acceptable**; no additional data are required for birds. Guideline and non-guideline studies, including an extensive ECOTOX literature search demonstrated that exposure to Quillaja saponins will not adversely affect birds. There are no concerns for non-target birds, including endangered species.
- 3b. Tier I Non-target Organism studies/data for fish acute toxicity are **Acceptable**. However, in non-guideline studies identified by BPPD, there are weak indications that long term exposure

(8-14 weeks) to high concentrations of Quillaja saponins (150 to 700 ppm) may have teratogenic and/or endocrine effects in fish (see Conclusion 3c).

- 3c. Therefore, since there is insufficient information regarding the potential for run-off following application of the product, the registrant must conduct a Fish Life Cycle toxicity study (OPPTS 850.1500) to alleviate concerns regarding potential teratogenic and/or endocrine effects in fish. Shifts in normal male:female ratios or any other potential teratogenic and/or potential endocrine effects in fish must be reported. (see Conclusions 3e & 3f)
- 3d. A non-guideline aquatic invertebrate acute toxicity study is **Acceptable**, although Daphnids would have been the preferred study organism. The study using Penaeid shrimp indicates that Quillaja saponins are slightly toxic to aquatic invertebrates. However, the same study also indicates that after 36-60 days exposure to Quillaja saponins, significant reductions in growth, feeding, and molting frequency were observed with a Lowest Observed Effect Concentration (LOEC) = 0.5 ppm and a No Observed Effect Concentration (NOEC) = 0.1 ppm.
- 3e. Based on the observed effects on fish (Nile tilapia) and an aquatic invertebrate (Penaeid shrimp), Tier II Environmental Fate data requirements are triggered. In lieu of these studies, the registrant must submit a credible rationale, supported with quantitative data, demonstrating that Quillaja saponins, when applied according to proposed label directions, will not run-off into aquatic sites in sufficient quantities to induce potential endocrine and/or teratogenic effects and/or will degrade with sufficient rapidity so as not to cause these effects. (see Conclusions 3c & 3f). The registrant is directed to 40 CFR 158.690 (d) Nontarget organism, fate and expression data requirements - Tier II. Protocols for these test Guidelines may be found in OPPTS Harmonized Guidelines Series 835 Fate, Transport and Transformation Guidelines.
- 3f. There is insufficient information regarding the amount of Quillaja saponins that may potentially run-off into aquatic systems via the various label application methods and rates, or as a result of unexpected precipitation events following application, and no information regarding the Estimated Environmental Concentrations (EEC) that may result from this potential run-off. Biotic and abiotic degradation/dissipation rates are also unknown. Proposed repeat applications to soil and foliage, and subsequent run-off, may increase Quillaja saponin concentrations in aquatic ecosystems to a level that will result adverse effects in fish and other aquatic organisms. Therefore, the data obtained from the studies described in Conclusion 3e above will be important for modeling degradation and aquatic EEC for Quillaja saponins.
- 3g. In lieu of the studies requested in Conclusions 3c & 3e, the registrant may request waivers from the aforementioned studies based on a scientifically credible rationale that includes quantitative information that can support the data requirements described for the requested studies. Otherwise, these data gaps will remain outstanding.
- 3h. A comprehensive Endangered Species Risk Assessment cannot be completed unless the deficiencies described in above are resolved.

- 4a. The registrant submitted data from 14 product performance (efficacy). The submitted efficacy studies DO NOT support proposed label use claims for control or suppression of parasitic nematodes or as a potential plant growth regulator;
- 4b. Only three studies were considered acceptable (MRIDs 466081-15, -16, and -17) and ONLY support proposed label claims for use of the product in controlling powdery mildew on squash.
- 4c. The remainder of the submitted efficacy studies are considered **Unacceptable** to support efficacy of the proposed EP for the following reasons:
- (i) In studies intended to evaluate control of nematodes, no nematode data were presented or the data did not demonstrate any significant differences;
 - (ii) One study supposedly conducted to evaluate nematode control, only presented only raw data without any statistical analysis or conclusions by the study authors;
 - (iii) some studies were intentionally or unintentionally combined with conventional chemical treatments, which invalidating the studies for purposes of evaluating the efficacy of Quillaja saponins.
5. The data do not support the registration of the end-use product at this time.
- 6a. At the proposed rates and methods of application on the proposed use sites, the data support the petition for an exemption from the requirements of tolerances. If the rates, methods, and/or use sites substantially change, a tolerance exemption would need to be re-evaluated.
- 6b. If new data become available demonstrating a potential for human dietary exposure to Quillaja saponins from all sources, including dietary exposure to Quillaja saponins from the applied product, will exceed the established ADI, tolerances may need to be established.

LABEL REVIEW

NOTE 3: The following is not a comprehensive label review. It pertains only to information used to support product chemistry data requirements, and risk assessments to humans and non-target organisms.

1. The active in ingredient name must be changed to Saponins of Quillaja saponaria (comprised primarily of QS-7, QS-17, QS-18, and QS-21).

NOTE 4: If the actual names of the saponins are available, they should be used in place of the QS numbers.

2. The concentration of active ingredient must be changed from 7.5% to 8.6%. Data reported in the five-batch analysis indicate that the true nominal concentration of Quillaja saponins is 8.6%.
3. Under Chemigation applications: provide additional information/explanation regarding the statement: *"If a pesticide tank is used, dilute the product with just enough water to assure an application concentration at the end of the irrigation line between 5,000 and 10,000 ppm."*

This appears to be an extremely high application rate that exceeds proposed label application rates. Furthermore, there is no recommended method to measure these concentrations.

4. The statement *"Avoid any runoff of this product in to waterways or ponds that would result in contamination of fish"* is not sufficient to prevent run-off of product due to human error or an unanticipated precipitation event.
5. Under Non-Agricultural Uses: Turfgrasses: The statement *"Do not apply within 10 feet of any surface body of water or fairway surface drain"* implies that this distance is sufficient to prevent run-off into these sites. At this time, there is insufficient information to determine whether 10 feet is a sufficient distance.
6. Label claims for nematicidal activity and plant growth regulator activity (i.e increases growth and yield) are not supported by the submitted efficacy studies. These claims must be removed.

STUDY SUMMARIES

Product Chemistry (MRIDs 465684-01 and -02)

Quillaja Extract, an EP, is intended for use as a nematicide, fungicide and plant growth regulator that is applied to the soil surface. No data/information were submitted for the TGAI.

The active ingredient is 8.60% Quillaja extract (NOTE: the registrant initially proposed 7.5%), based on the data submitted in the 5-batch analysis. However, the identities of the major saponins in the extract (identified only as QS-7, QS-17, QS-18, and QS-21, and their individual concentration percentages in the extract were not listed; this information is required. The EP contains approximately [REDACTED] impurities, but the individual impurities are not individually identified on the CSF. MRID 46568401 indicates that the impurities are "coextractives of the active ingredient, and were derived from the same organism" and coextractives include [REDACTED]

[REDACTED] The registrant must list the impurities that occur at concentrations $\geq 0.1\%$ on the CSF.

Intentionally added inerts (other) ingredients are [REDACTED]

[REDACTED]. [REDACTED] The description of starting materials and the production process are adequately addressed. No chemical reactions occur during the manufacturing process. No unintentional ingredients are present in the EP other than those

impurities (coextractives) present in, and carried over from the starting ingredient. Five production lots of Quillaja Extract were analyzed for content of active ingredient saponins, water, and impurities. The mean measured saponin content was 8.6% (range: 7.91-9.20%), not the 7.5% listed on the CSF. [REDACTED]

[REDACTED] The enforcement analytical method is a gradient elution HPLC. The test solution is analyzed by gradient elution HPLC versus a calibrant prepared from material of known saponins content. The physical/chemical properties are acceptable, but incomplete. Data/information for Color, Odor, Stability, and Boiling Point remain outstanding.

TABLE 1. Physical and Chemical Properties for Quillaja Saponin Extract^a

Guideline Reference No./Property	Description of Result
830.6302 Color	Not reported, but is required for the TGAI/EP
830.6303 Physical State	Liquid at room temperature
830.6304 Odor	Not reported, but is required for the TGAI/EP
830.6313 Stability	Not reported, but is required for the TGAI/EP
830.6314 Oxidation/Reduction: Chemical incompatibility	Product contains nominally 67% water and none of the ingredients is a strong oxidant or reductant.
830.6315 Flammability	Product is not flammable and contains nominally 67% water and no volatile or flammable components.
830.6316 Explodability	Not addressed; product contains 67% water and no explosive ingredients.
830.6317 Storage Stability	Stable for at least two years when stored in the original container.
830.6319 Miscibility	Not relevant to the proposed use. Product will not be used with non-aqueous solvents.
830.6320 Corrosion Characteristics	Product contains nominally 67% water and none of the ingredients is a strong oxidant or reductant.
830.6321 Dielectric Breakdown Voltage	Not applicable, product is not intended for use around electrical equipment.
830.7000 pH	4.19 under ambient conditions
830.7050 UV/Visible	Not applicable
830.7100 Viscosity	29-37 mPa s (kinematic viscosity)
830.7200 Melting Range	Not applicable; product is liquid at room temperature.
830.7220 Boiling Range	Not reported, but is required for this TGAI/EP
830.7300 Bulk Density	1.1435-1.1438
830.7370 Dissociation Constant in Water	Not applicable; does not dissociate
830.7520 Particle Size/Distribution	Not applicable
830.7550 Partition Coefficient	Not applicable
830.7840 Water Solubility	Product is aqueous
830.7950 Vapor Pressure	Product does not vaporize at room temperature and does not

TABLE 1. Physical and Chemical Properties for Quillaja Saponin Extract ^a	
Guideline Reference No./Property	Description of Result
	have a measurable vapor pressure.

^a Data from MRID 465684-02.

Classification: **UNACCEPTABLE**, but upgradable. To upgrade to acceptable, the registrant must resolve the deficiencies listed in Conclusions 1a through 1d; and 2a through 2g above.

Tier I Toxicity (MRIDs 463536-05 to -10)

Acute toxicity study data are summarized in Table 2 below. The product is in Toxicity Category III for oral and dermal toxicity, Toxicity Category II for acute inhalation toxicity and primary eye irritation, and Toxicity Category IV for primary dermal irritation; it is not a dermal sensitizer. Quillaja saponins are not genotoxic or mutagens. They have no teratogenic effects and are not immunotoxic. They have no subchronic or chronic oral toxicity. When applied according to label directions, there will be no acute, subchronic, or chronic exposure via ocular, dermal, or inhalation routes of exposure when appropriate PPE (Toxicity Category II) is used by applicators/handlers (including use of goggles and respirators when product is applied using spray equipment). Detailed summaries are discussed below Table 2.

Table 2. Acute, Subchronic and Chronic Toxicity and Primary Irritation/Sensitization data for Saponins of *Quillaja saponaria*¹

Study/Guideline No.	Results	Toxicity Category	MRID No.
Acute Oral Toxicity OPPTS 870.1100	LD ₅₀ >3000 mg product/kg Acceptable	III	466081-01
Acute Dermal Toxicity OPPTS 870.1100	LD ₅₀ >4000 mg product./kg Acceptable	III	466081-02
Acute Inhalation Toxicity OPPTS 870.1300	No study submitted; waiver requested. Waiver Unacceptable , but upgradable (see Conclusions 2b & 2c).	II ²	466081-10
Primary Eye Irritation OPPTS 870.2400	Corneal opacity was noted on 3/3 rabbits at 24 hours post-instillation with symptoms clearing on one rabbit by 48 hours, on another rabbit by 72 hours, and persistence on the third rabbit through 72 hours. Acceptable	II ³	466081-03
Primary Dermal Irritation OPPTS 870.2500	Moderate to very dermal irritation effects to 48 hrs; symptoms cleared by 72 hours after patch removal; not an irritant Acceptable	IV	466081-04

Study/Guideline No.	Results	Toxicity Category	MRID No.
Skin Sensitization OPPTS 870.2600	Test and naive control animals showed no positive signs of reactivity 24 and 48 hours after challenge. Acceptable	Not a sensitizer	466081-05
Genotoxicity, Immune Response, & Teratogenicity OPPTS 870.5000, 880.3550, & 870.3700	No studies submitted; waivers requested based on long history of oral acute and chronic exposure to humans in food. The a.i. is also an EPA List 4A Inert and is an FDA-approved flavoring agent and food additive (21 CFR 172.510). Acceptable	Not genotoxic or a mutagen	466081-10
90-day Feeding OPPTS Non-guideline studies	NOAEL (rat, male) = 2470 mg/kg/d NOAEL (rat, female) = 3030 mg/kg/d Unacceptable, but upgradable (see Conclusion 2d)	No subchronic oral toxicity is expected ⁴	466081-06
90-day Dermal Toxicity OPPTS 870.3250	No studies submitted; waiver requested based on lack of prolonged human dermal exposure and no intentional application to human skin. No toxicity in oral acute and chronic studies; dermal metabolism not expected to differ from oral metabolism. The a.i. is also an EPA List 4A. Acceptable	No subchronic dermal toxicity	466081-10
90-day Inhalation OPPTS 870.3465	No study submitted; waiver requested. Waiver Unacceptable , but upgradable (see Conclusions 2b & 2c).	-	466081-10
Combined chronic toxicity/carcinogenicity Non-guideline.	84-wk NOAEL (mouse) > 700 mg a.i./kg/d 84-wk LOAEL (mouse) = 2200 mg a.i./kg/d ⁵ 2-yr NOAEL (rat) > 1500 mg/kg/d Acceptable	Not a chronic toxicant; not a carcinogen	Phillips, et al. (1979) Drake, et al. (1982)

¹ Test substance was the EP containing 8.6% Quillaja extract.

² Classified by BPPD in lieu of an acceptable study or waiver request; based on potential for primary eye irritation.

³ The test substance is conservatively considered to be at least a moderate irritant, although it is not corrosive. Since it is not known when corneal opacity would have cleared, the primary eye irritation study is classified in **Toxicity Category II**.

⁴ Based on a lack of toxicity in long term chronic studies.

⁵ Based on reduced body weight that was due to reduced food intake; reduced food intake likely due to taste aversion to saponins.

Acute Oral Toxicity: Three male and three female Sprague-Dawley Crl:CD[®](SD)IGS-BR rats were administered 3000 mg Quillaja extract/kg body weight by oral gavage and observed for

mortality and clinical signs of toxicity during the first several hours post-dosing and daily for 14 days. All animals were euthanized and necropsied at the end of the study. All rats survived and gained weight during the study. Drowsiness, "adynamia" and slight depression were noted in all rats one hour post dosing with recovery of two males by 24 hours and one male and three females by 48 hours. Necropsies were negative. For male, female, and male and female combined rats, the **acute oral LD₅₀ was >3000 mg product/kg (Acceptable; Toxicity Category III).**

Acute Dermal Toxicity: Five male and five female Sprague-Dawley Crl:CD[®](SD)IGS-BR rats were administered 4000 mg Quillaja extract/kg body weight that was applied evenly over the shaved area (approximately 10% of the total body surface) of the dorsal trunk. The test animals were observed during the first several hours after treatment for mortality and clinical signs of toxicity and daily thereafter for 14 days. All animals were euthanized and necropsied at the end of the study. All rats survived and gained weight during the study. There were no clinical signs of toxicity and necropsies were negative. For male, female, and male and female combined rats, the **acute dermal LD₅₀ was >4000 mg product/kg (Acceptable; Toxicity Category III).**

Acute Inhalation Toxicity: No studies were submitted. In lieu of an acute inhalation study, the registrant requested a waiver based on: (i) an estimate of exposure using the Pesticides Handlers Exposure Database (PHED); (ii) low toxicity of the active ingredient in oral chronic and subchronic studies; (iii) long history of human oral exposure to Quillaja saponaria extracts; and (iv) Quillaja saponaria is an approved inert on EPA's List 4A. **(Unacceptable, but upgradable, pending revision of product label to reflect Toxicity Category II; Toxicity Category II).**

The registrant assessed inhalation risk by comparing inhalation exposure to oral toxicity values. The registrant-generated exposure assessment did not address the potential for the product to cause irritation to mucosal membranes and lung tissue. The registrant must either conduct an acute inhalation study, submit a credible rationale that supports a waiver from the requirements of an acute inhalation study, or **accept Toxicity Category II** for acute inhalation toxicity together with a Signal Word, Precautionary Statements, and First Aid Statements appropriate for Toxicity Category II, that requires the use of respirators whenever spray application methods are used.

Primary Eye Irritation: Three young adult New Zealand rabbits were administered 0.1 mL Quillaja extract/eye/animal (undiluted) by instillation into the conjunctival sac of one eye, and the eye held closed for approximately one second. The other eye served as control. The eyes were examined and scored 1, 24, 48 and 72 hours after test material instillation. Corneal opacity was noted on 3/3 rabbits at 24 hours post-instillation with symptoms clearing on one rabbit by 48 hours, on another rabbit by 72 hours, and persistence on the third rabbit through 72 hours. The test substance is conservatively considered to be at least a moderate irritant, although it is not corrosive. Since it is not known when corneal opacity would have cleared, the primary eye irritation study is classified in **(Acceptable; Toxicity Category II).**

Primary Dermal Irritation: Three young adult New Zealand rabbits were administered 0.5 mL of Quillaja extract applied on a 6 cm² clipped intact dose site, and the site covered with a gauze patch. The covering was removed 4 hours later, the site cleansed, and dermal examination was

recorded at 1, 24, 48, and 72 hours after patch removal. All rabbits survived the study. Very slight erythema was noted on 3/3 rabbits one hour after patch removal with clearance on one rabbit by 24 hours and on two rabbits by 48 hours. No symptoms were observed at 72 hours **(Acceptable; Not a dermal irritant; Toxicity Category IV)**.

Skin Sensitization: Thirty-three male Hartley guinea pigs were induced and challenged according to the method of Buehler. For the induction, 0.5 mL undiluted Quillaja extract was used. Twenty-eight days after the first induction, the test and control animals were challenged with 0.5 mL of undiluted Quillaja extract under occlusion to naive sites. Animals were evaluated 24 and 48 hours following induction and challenge application. All animals survived the study. The test animals showed no skin reaction after challenge. **(Acceptable; Not a Sensitizer)**.

90-Day Feeding (OPPTS 870.3100): Quillaja extract (purity, batch/lot # not provided) was administered to 15 CFE rats at dietary concentrations equivalent to 0, 360, 1180, or 2470 mg/kg bw/day for males and 0, 440, 1370, or 3030 mg/kg bw/day for females) for 13 weeks. Additional groups of 5 rats were administered 0, 2.0, or 4.0% test material for 2 weeks or 6 weeks for interim evaluations. There were no treatment-related effects on mortality, clinical signs, hematology and erythrocyte osmotic fragility, clinical chemistry, urinalysis and urine concentration and dilution test results, or gross and histologic pathology. High-dose males had a mean weight loss during the first 24 hours (data not available) followed by statistically significant decreases in absolute body weight (at least 4-8% less than controls) until day 78, and the cumulative body weight gain of this group was 89% of controls. High-dose females had statistically significant decreases in absolute body weight during the first two weeks of treatment (data not available), and mid- and high-dose females had marginally decreased body weight gain over the 0-29 day interval (both 92% of controls). Markedly decreased food consumption was seen on day 1 at the mid- and high-dose treatment levels in both sexes (males: 76% and 48%; females 85% and 41% of controls, at the mid- and high-concentrations respectively; n.s.). Mid- and high-dose males also had decreased mean overall water consumption (90% and 82% of controls; $p < 0.05$ and $p < 0.001$, respectively). Decreased absolute and relative liver weight were seen in males at the 2.0% and 4.0% dietary concentrations at weeks 2, 6, and 13, but it is unlikely that these resulted from direct toxicity of the test material on the organ themselves as there were no correlated clinical chemistry changes at any of the time points, and no histopathological changes were noted at week 13. **Based on the data, the NOAEL for the study would be the highest dose tested; 4.0% in the diet (2470 mg/kg/day for males and 3030 mg/kg/day for females).**

(Unacceptable, but upgradable pending submission of the method used to prepare the diet formulations, and the storage conditions for the test material and the diet formulations are provided and found to be acceptable.

Carcinogenicity/Chronic toxicity (Non-Guideline): A non-guideline study was submitted (Drake et al., 1982). Groups of 48 male and 48 female Wistar rats were administered Quillaja extract at concentrations of 0, 0.3, 1.0, and 3.0% for 2 years. The equivalent doses in mg/kg bw/day were 120, 390, and 1175 for males, and 147, 497, and 1500 for females. No treatment-related toxic effects or mortality were observed. Although not statistically significant, high dose males and females weighed 8% and 7% less than controls, respectively, by the end of the 106 week study period. The average daily food consumption by all treated males and females was generally 1-10%

less than controls, although there were measurement intervals when both sexes consumed more than controls by as much as 12-16% in a manner that was not dose related. No treatment-related effects were observed on hematologic, clinical chemistry, or urinalysis parameters. Necropsies were negative. The incidence of benign tumors and carcinomas of the thyroid, pituitary, and peritoneal cavity were either not statistically different from controls, or fell within the spontaneous incidence rate for the Wistar rat. The lowest-observed-adverse-effect level (LOAEL) of Quillaja extract in rats was not identified for either sex. **The no-observed-adverse-effect level (NOAEL) was 3.0% in the diet (1175 mg/kg/day for males and 1500 mg/kg/day for females). Quillaja extract was not a chronic toxicant nor was it a carcinogen in the rat under the conditions of this study.**

An earlier non-guideline study was also submitted that gave similar results (Phillips et al., 1979). Groups of 48 male and 48 female TO-strain mice were administered Quillaja extract at concentrations of 0, 0.1, 0.5, and 1.5% for 84 weeks. There were no treatment-related effects on death rate or any histopathological factors, including tumors, although there was reduced body weight gain at the highest dose (equivalent to 2200 mg/kg/day). Reduced body weight was associated with reduced food intake, which may have been caused by aversion of food treated with high levels of saponins. **The NOAEL was 700 mg Quillaja extract/mg/day. Quillaja extract was not a chronic toxicant nor was it a carcinogen in the rat under the conditions of this study.**

Other Tier I Toxicity Data Requirements (MRID 466081-10)

No studies were submitted for the remainder of the Tier I Toxicity data requirements. In lieu of studies, the registrant submitted a group of waiver requests (MRID 466081-10) that contains supporting literature reviews on the health, toxicological, and environmental effects of saponins obtained from a number of plant sources, including *Quillaja saponaria*. A list of 9 pertinent references is included. This list is supplemented by scientific literature obtained by the BPPD reviewer. The remaining Tier I Toxicity Data summarized below are discussed in detail in the Human Health Risk Assessment.

90-Day Inhalation Toxicity (OPPTS): No studies were submitted. In lieu of a study, the registrant requested waivers based on lack of prolonged human dermal exposure and a lack of toxicity via the oral route of exposure. The waiver request is **Unacceptable**. The waiver rationale did not address the potential for irritation of mucosal membranes and/or lung tissue of applicators/handlers when the product is applied via multiple spray applications. Since the product is classified in Toxicity Category II for Primary Eye irritation, it is likely the product will be an irritant via the inhalation route of exposure. Therefore, similar to BPPD requirements described above under acute inhalation toxicity, respirators will be required for applicators/handlers to mitigate exposure. If deficiencies identified in the acute inhalation toxicity summary above are resolved, a 90-day inhalation toxicity study will not be required.
(Unacceptable, but upgradable)

Teratogenicity, Genotoxicity and Immune Response (OPPTS 870.3700, 870.5100 and 870.7800):

No teratogenicity, genotoxicity or immune response studies are required. Humans (including

females and children) are regularly exposed to Quillaja saponins via its use as an FDA-approved flavoring agent and food additive (21 CFR 172.510) and as an inert of minimal concern (EPA List 4A) in other pesticides. Undiluted *Quillaja saponaria* extracts are used in soft drinks at levels of 100-500 mg/kg (WHO, 2002). The Joint WHO/FAO Expert Committee on Food Additives (JEFCA, 2002) established an acceptable daily intake of Quillaja saponins of up to 5 mg/kg/day. The mean intake of Quillaja extracts in the U.S. from soft drinks (the major food use) is up to 0.54 mg/kg/day, or 11% of the ADI (WHO, 2005); Quillaja extracts are also used in as emulsifiers in baked goods, candies, frozen dairy products, gelatin, and puddings. The active ingredient is not a mutagen nor is it related to any known classes of mutagens. Chronic feeding studies (84-wk and 2-yr) have demonstrated that Quillaja saponins are not carcinogenic in mice and rats fed Quillaja saponins in the diet at up to 2200 mg/kg (Phillips et al., 1979; Drake et al., 1982). Saponins have been demonstrated to have anticarcinogenic properties (Li et al., 2002; Rao and Sung, 1995) and to stimulate the immune system (Kenarova et al., 1990; Wu et al., 1990). Dietary levels of Quillaja saponin (up to 700 ppm in feed) stimulated the immune systems of piglets fed for 20 days post-weaning (Ilsey et al., 2005).

90-Day Dermal Toxicity (OPPTS): No studies were submitted. In lieu of a study, the registrant requested waivers based on lack of prolonged human dermal exposure; no to low toxicity in oral acute and chronic studies; dermal metabolism not expected to differ from oral metabolism. The product was demonstrated to have no acute dermal toxicity ($LD_{50} > 4000$ mg/kg), was not a dermal irritant, and was not a sensitizer in a Guideline studies (MRIDs 466081-02, -04, & -05, respectively) and the active ingredient is currently on EPA's List 4A Inerts of minimal concern. Label statements for PPE that require applicators and handlers to wear long-sleeved shirts and long pants, chemical resistant gloves made of waterproof material, and shoes and socks will mitigate dermal exposure.

Tier I Non-Target Organisms (MRIDs 465684-12 & 466081-09)

Non-target organism toxicity study data are summarized in Table 3 below. The data include studies and scientific literature submitted by the registrant, and an extensive scientific literature search, including a search of EPA's ECOTOX database, conducted by BPPD. The product is practically non-toxic to birds and fish on an acute and dietary basis, and there have been no reports of adverse effects to plants in efficacy studies using the product. Quillaja saponins are slightly toxic to aquatic invertebrates (Penaeid shrimp). The contact toxicity of Quillaja saponins on non-target insects is unknown.

There were two reports of potential reproductive effects (low egg production, shift in the 1:1 male:female ratio toward more males) in the fish Nile tilapia (*Oreochromis niloticus*) when fed diets containing high Quillaja saponin content (300 ppm and 700 ppm, respectively) under laboratory conditions (Francis et al., 2001 and 2002c). An extensive literature search, including a search of EPA's ECOTOX database did not discover any other literature regarding Quillaja saponins and reproductive effects in wildlife or humans. In contrast, Quillaja saponins have been demonstrated to stimulate fish growth and metabolism (Francis et al., 2002a & 2002b); and stimulate fish immune systems to resist disease (Grayson et al., 1987; Galindo-Villegas &

Hosokawa, 2004). Female pigs administered 2.5 g saponin in feed throughout gestation had significantly fewer stillborn piglets than female pigs fed saponin-free diets (Ilsey and Miller, 2005).

Table 3. Non-target Organism Toxicity Data for Saponins of *Quillaja saponaria*¹

Study/Guideline No.	Results	Toxicity Category	MRID No.
Avian Acute Oral Toxicity OPPTS 850.2100	LD ₅₀ >2250 mg product./kg Acceptable	Practically non-toxic	465684-12
Avian Dietary Toxicity OPPTS 850.2200 Non-guideline study	28-day LD ₅₀ > 9000 ppm 28-day LOAEL = 9000 ppm 28-day NOAEL > 3000 ppm Acceptable	Practically Non-toxic	Jenkins and Atwal (1994) 466081-10
Fish LC50 <i>Cyprinus carpio</i> (carp) OPPTS 870.3450	LD ₅₀ >100 ppm product ² Acceptable	Practically Non-toxic	466081-09
Fish Feeding Studies <i>Cyprinus carpio</i> (carp) Non-guideline	8-wk 150-300 ppm QS in feed increased growth and metabolic rate Acceptable	No toxic effects observed	Francis et al., 2002a; & 2002b.
Two Fish Feeding Studies <i>Oreochromis niloticus</i> (Nile tilapia) Non-guideline	17-day old fry fed dietary QS up to 700 ppm in feed for 8-wk; increased growth rate shift in 1:1 male:female ratio towards males was observed at all dose levels, was statistically significant at highest dose Supplemental	No toxic effects observed; but possible endocrine effects	Francis et al., 2001; & 2002c.
	Adult tilapia fed dietary QS at 150-300 ppm in feed for 14 weeks At 150 ppm: 1 of 2 females prod. no eggs At 300 ppm: 2 of 2 females prod. no eggs Supplemental	No toxic effects observed; but potential teratogenic effects	
Aquatic Penaeid Acute Toxicity (Aquatic Invertebrate) OPPTS 850.1045 Non-guideline	48-hr EC ₅₀ = 20.83 ppm (mortality) Acceptable	Slightly toxic	Chen et al., 1996 466081-10
	36-day LOEC = 1 ppm 60 day LOEC = 0.5 ppm 60 day NOEC = 0.1 ppm (based on reduced growth, feeding, molting frequency) Supplemental	-	
Non-target Plant Toxicity	No toxic effects reported in any efficacy studies	No toxic effects observed	-
Non-target Insect toxicity	No studies or waivers submitted Unacceptable	Unknown	-

¹ Test substance was the TGAI/EP containing 8.6% Quillaja extract (as determined by five-batch analysis).

² Test substance was QL-35B containing 34.4% Quillaja extract (as determined by brixometer).

Avian Acute Oral Toxicity (OPPTS 850.2100): Groups of 10 northern bobwhite (*Colinus virginianus*) were administered a single nominal oral dose of 0, 292, 486, 810, 1350, or 2250 mg of Quillaja Extract/kg body weight and observed for 14 days. Signs of toxicity in one or more birds in test groups receiving ≥ 486 mg/kg included anorexia, erect posture, or ruffled/slightly ruffled appearance, resolving in most birds by test day 4 or earlier. One 2250 mg/kg group male was found dead on day 2 after exhibiting ruffled appearance, reduced reaction to external stimuli, and loss of coordination. Mean body weight for test days 0-3 was reduced in males of the 1350 mg/kg group and females of the 2250 mg/kg group, but was comparable to that of controls afterward. Mean feed consumption for days 0-3 was reduced in both sexes in the 1350 and 2250 mg/kg groups, but was comparable to that of controls afterward. The **acute oral LD₅₀ was >2250 mg Quillaja Extract/kg body weight (practically non-toxic)**, the highest dose tested. The **no-mortality level was 1350 mg/kg** (the single mortality was likely not treatment-related), and the **no-observed-effect level (NOEL) was 292 mg/kg** (based on food aversion, erect posture, and/or ruffled appearance). **Toxicity Category: Practically non-toxic.**

Avian Dietary Toxicity (OPPTS 850.2100): No study was submitted. In lieu of a study, the registrant submitted a waiver request supported by a study obtained from the technical literature (Jenkins and Atwal, 1994). In this study, 200, 1-day old, unsexed chicks, Meat Strain 31, and fed Quillaja saponins (QS) at 0.1, 0.3, and 0.9% [equivalent to 1000, 3000, and 9000 ppm (mg QS/kg feed)] in the diet for 28 days. All chicks survived and gained weight throughout the study. Weight gain was significantly reduced only at the highest dose (9000 ppm) which was associated with reduced food intake. Other effects at the high dose included reduced lipid digestibility and increased cholesterol excretion, but there were no effects on blood concentration of total cholesterol or of high density lipoprotein (HDL) cholesterol. There was equivocal evidence that absorption of vitamins A and E was reduced. Otherwise, no clinical signs of toxicity were reported for chicks at any dose level. Based on reduced food intake and subsequent weight gain, **the LOAEL = 9000 ppm QS and the NOAEL >3000 ppm QS in the diet. Toxicity Category: Practically non-toxic. Acceptable**

Freshwater Fish LC₅₀, and Freshwater/Marine Invertebrate LC₅₀ (OPPTS 850.1075, 850.1300 and 850.1035): In a 96-hour static-renewal bioassay, common carp (*Cyprinus carpio*) were exposed to a nominal concentration of 100 mg/L QL Agri 35°B (Quillaja Extract) in dechlorinated tap water. Control fish were exposed to dechlorinated tap water only. There was no mortality in the treatment or control groups, and all fish appeared normal during the test. The 96-hour LC₅₀ for common carp in this test was >100 mg/L. **Toxicity Category: Practically non-toxic. Acceptable (if 34.4% test substance is equivalent to the TGA)**

In two non-guideline studies obtained by BPPD, Nile tilapia administered diets containing up to 300-700 ppm Quillaja saponin (QS) had higher growth rates than untreated controls (Francis et al., 2001; Francis et al., 2002c). However, at dietary levels of 150 ppm QS for 14

weeks, one of two female fish failed to produce eggs, and at the 300 ppm dietary level, both treated females failed to produce eggs. Control females and one female in the 150 ppm dose level produced eggs once every 14 days (Francis et al., 2001). In the second study, dietary levels of 700 ppm QS for 6 months induced a change in the normal 1:1 male:female sex ratio towards a significantly higher number of males (Francis et al., 2002c). These data would indicate that chronic exposure to dietary saponins may be fish reproductive toxicants at 300 ppm and endocrine disruptors at 700 ppm. It is noted here that the aforementioned studies were conducted under laboratory conditions by the same investigators and that no other studies are available that demonstrate similar reproductive or endocrine-related effects in fish. **Supplemental. These studies suggest that there may be potential teratogenic and/or endocrine effects in fish.**

In a non-guideline study submitted by the registrant (Chen et al., 1996), Kuruma shrimp (*Penaeus japonicus*) were exposed to seven levels of purified Quillaja saponin (15 to 30 ppm) in a flow-through system for up to 96 hours. The 24-, 48-, 72-, and 96-hr EC50 were 27.08, 20.83, 18.91, and 18.14 ppm, respectively. **Toxicity Category: Slightly toxic. Acceptable**

In the same study discussed above, the investigators also evaluated the effects of Quillaja saponins on growth. After 36-60 days exposure, significant reductions in growth, feeding, and molting frequency were observed with a Lowest Observed Effect Concentration (LOEC) = 0.5 ppm and a No Observed Effect Concentration (NOEC) = 0.1 ppm. **Supplemental. Potential adverse effects on aquatic invertebrates with chronic exposure.**

Non-target Plant Studies (OPPTS 850.4100): No non-target plant studies were submitted, but none are required. No plant toxicity was observed in any product efficacy trials conducted by the registrant (see MRIDs 466081-11 to -24; & 466310-01) using a test substance that contained 35% active ingredient. Furthermore, saponins are widespread in plants and triterpenoid saponins (such as those present in the active ingredient) are common in many cultivated crops (Oakenfull, 1981). The product is not intended for use on forests or grasslands. **Acceptable, no additional data are required.**

Non-target Insect Studies (OPPTS 850.3030 and 850.3040): No non-target insect studies or waiver requests were submitted. Little data are available regarding the effects of Quillaja saponins (QS) on insects, except for a laboratory study on mosquitoes (Weisman and Chapagain, 2003). In this study, it was demonstrated that after two day exposure to 500 and 1000 ppm QS, larval survival was reduced approximately 60% and 98%, respectively. An ECOTOX search reported the following saponin mortality data for larval mosquitoes: *Culex fatigans* 24-hr LC50 = 58 ppm (Tabassum et al., 1993). It is Based on these data, other aquatic non-target larvae may be adversely affected via run-off or spray drift. **Unacceptable. Non-target insect studies/data specific to Quillaja saponins (using the TGAI if testing is conducted) are required.**

Product Performance (Efficacy)

The registrant submitted summaries of 14 efficacy studies (MRIDs 466081-11 to -24; & 466310-01) conducted to evaluate the efficacy of a 35% Quillaja Extract formulation as a tank mix with a herbicide, as a fungicide, nematocide, plant growth regulator, and herbicide adjuvant.

It is noted that there were no reports of phytotoxicity in any of the treated crops.

As a group, the efficacy studies are unacceptable for use in supporting proposed label claims. The proposed EP contains 8.6% active ingredient whereas the test substance used in efficacy testing contained 35% active ingredient - approximately a four-fold increase.

The data do not support label claims for nematocidal activity or plant growth regulator activity. Limited data indicate that the product is effective in suppressing powdery mildew infestations in squash.

See attached Efficacy studies for details.

RISK ASSESSMENT - Overview

[NOTE: information below summarized by BPPD reviewer from a published literature review cited by the registrant (WHO, 2002) with some additions by the BPPD reviewer].

General Information on Saponins: Saponins are naturally-occurring glycosides, produced mainly by plants, that form soap-like foams in aqueous solution. Saponins are comprised of a sugar moiety (typically glucose, galactose, glucuronic acid, xylose, rhamnose, or methylpentose) linked to a hydrophobic aglycone (sapogenin) at the C-3 (monodesmosidic) or at the C-3 and C-26 or C-28 (bidesmosidic) positions (see review by Francis et al., 2002). The aglycone may be a triterpenoid or steroid. Saponins are found in wide variety of plants of diverse species, many of which are used in human food. Saponins derived from quillaja are bidesmosidic triterpenoids. Hydrolysis of quillaja saponins yields free monosaccharides (see above) and the triterpenoid aglycone. Saponins derived from the bark of *Quillaja saponaria* (Soapbark tree), an evergreen tree native to the arid Andes region of South America, have been the most extensively studied. In quillaja, saponins are found primarily in the tree bark and wood, and to a lesser extent in the leaves. The wood and bark are typically boiled in water, the water extract filtered and then concentrated by evaporation. Quillaja saponins are widely used as emulsifiers, flavoring agents, and foaming agents in foods, soft drinks, and beer (Cheeke, 1999; WHO, 2002).

Biological Effects of Saponins: The precise role of saponins in plants is not well defined. Some saponins, such as avenacosides A & B (from oats) are activated by plant enzymes in response to physical damage or pathogen infection (Deacon, 2005). Other saponins have antimicrobial or insecticidal activity. *In vitro* studies have demonstrated that saponins have hemolytic activity (i.e. lysis of red blood cells) based on the affinity of the aglycone moiety

for certain components in membranes, resulting in the development of pores, although the precise mechanisms are complex and still under investigation. In general, monodesmosidic saponins have more hemolytic activity than bidesmosides. Other *in vitro* studies indicate that some saponins increase permeability of intestinal mucosal cells, reducing active transport by these cells, while facilitating "uptake of substances that are not normally absorbed" (Gee et al., 1989). However, *in vivo* biological activity on intestinal cells is less clearly understood due to the uncertainty of interactions with other substances normally found in intestines. Depending on the plant source of saponins and the type of saponin studied (monodesmosides or bidesmosides), both beneficial and adverse effects have been reported for saponins ingested by animals. Some saponins are toxic to fish, molluscs, and protozoa (see review by Francis et al., 2002), whereas others have been shown to stimulate fish growth and metabolism (Francis et al., 2002) and stimulate the immune systems of fish and pigs (Grayson et al., 1987; Ilsey et al., 2005). Saponins have also been shown to antifungal and antiviral activity (Favel et al., 1993). Beneficial effects of dietary saponins include stimulation of the immune system, lowering of blood serum cholesterol, anticarcinogenic and antioxidant properties (Kenarova et al., 1990; Li et al., 2002; Oakenfull and Sidhu, 1990; Rao and Sung, 1995; Wu et al., 1990). With the data currently available for saponins, the function and structure-activity relationships have not yet been clearly established.

[NOTE: the following information was summarized and re-organized by BPPD reviewer from literature citations submitted by the registrant in MRID 466080-10. The listed citations are those used by the registrant with additions made by the BPPD reviewer].

Occurrence of Saponins in Plants Used for Human Food: Saponins are found in a large number of plants used for human food, flavoring, herbs, and spices (Oakenfull and Sidhu, 1989; Oakenfull, 1981; Lasztity et al., 1998). Up to 100 mg saponin has been measured in a kg of sugar extracted from sugar beets (*Beta vulgaris*) and soybean flour and soybean protein has been shown to contain up to 2.5% saponin (Oakenfull, 1981; Sancho et al., 2000). It has been estimated that saponins comprise the pharmacologically active components of approximately 30% of all medicinal plants (Balandrin, 1996; Liu, 1995). Quillaja saponin extracts, derived from the bark of the Soapbark tree (*Quillaja saponaria*) are recognized as FDA GRAS and has an average daily intake (ADI) of 5 mg/kg/day established by the Joint Expert Committee on Food Additives (JEFCA) (WHO, 2002).

Description of the Quinoa Source Material (MRID 463536-11): Quillaja saponin extract is obtained from the bark of the Soapbark tree (*Quillaja saponaria*), an evergreen which is native in the South American Andes region.

Description of the TGA/EP (MRIDs 463536-01 to -04): Quillaja Extract (EPA File Symbol No. 82572-R) is a biological extract and an end-use product (EP) intended for use as a nematocide, fungicide, and plant growth regulator on grapes, citrus, pome/stone fruit, tree nut crops, strawberry, cucurbits, leafy vegetables, cole crops, bulb vegetables, root and tuber crops, ornamental bulbs, avocado, and turf. The product is intended to be applied pre- and post-plant to the soil via shank injection, ground spray equipment and low pressure irrigation

equipment (drip, tube strip, sprinkler) to control nematodes or as a plant growth regulator; and for foliar applications as a fungicide.

Product Chemistry: The active ingredient is an water extract of *Quillaja saponaria*; the saponin content of the EP is 8.6%. There is no discrete TGAI. There are approximately 60 bidesmosidic triterpenoid saponins in quillaja extracts, with the four major saponins designated as QS-7, QS-17, QS-18, QS-21 (WHO, 2002); of the four major saponins, QS-18 predominates (see 5-batch analysis, MRID 466081-01). The major saponins are derivatives of quillaic acid. The remainder of the product consists of coextractives, including [REDACTED]

[NOTE: The following information was obtained from the product label]

Application Methods and Rates: According to the proposed Draft Label:

Methods (from the draft label): "*Quillaja Extract may be applied using ground equipment with a band sprayer, soil/fertilizer shanks, injected through drip irrigation equipment or through above ground sprinkler systems.*"

THE FOLLOWING EXPOSURE CALCULATION

A. Maximum Use Rates (nematode suppression) with no more than 6 applications per season:

Grapes, Citrus, Pome/Stone Fruits, Nut crops: Up to 4 gal product/A/application (app.) for the first app., followed as needed every 7-14 days depending on crop) for up to 6-10 weeks (but no more than 5 additional apps.) at 1 quart (qt)/A. Therefore,

$$\begin{aligned} 4 \text{ gal/A/app} \times 9.6 \text{ lbs/gal (product density)} \times 0.086 \text{ (8.6\% a.i.)} &= \mathbf{3.3 \text{ lbs a.i./A (1}^{\text{st}} \text{ app.)}} \\ 0.25 \text{ gal/A/app} \times 9.6 \text{ lbs/gal} \times 0.086 &= \mathbf{0.2 \text{ lbs a.i./A/app}} \times 5 \text{ apps} = \mathbf{1.03 \text{ lbs a.i./A}} \\ 3.3 \text{ lbs a.i./A} + 1.03 \text{ lbs/A} &= \mathbf{4.3 \text{ lbs a.i./A/yr}} \end{aligned}$$

Strawberries: Up to 4 gal product/A/app 3-7 days pre-plant, then followed as needed for up to 4-6 weeks (but no more than 5 additional apps.) at 1 quart (qt)/A. Therefore,

$$\begin{aligned} &\mathbf{3.3 \text{ lbs a.i./A (1}^{\text{st}} \text{ app. pre-plant)}} \\ 0.25 \text{ gal/A/app} \times 9.6 \text{ lbs/gal} \times 0.086 &= \mathbf{0.2 \text{ lbs a.i./A/app}} \times 5 \text{ apps} = \mathbf{1.03 \text{ lbs a.i./A}^*} \\ 3.3 \text{ lbs a.i./A} + 0.2 \text{ lbs/A} &= \mathbf{4.3 \text{ lbs a.i./A/yr}} \end{aligned}$$

*Only potential for foliar exposure

Fruiting Vegetables, Cucurbits, Leafy Vegetables, Cole Crops: Up to 4 gal/A (single app) 1-7 days prior to planting. Therefore,

3.3 lbs a.i./A/yr (no foliage exposure)

Bulb/Root/Tuber/Ornamental Bulb Crops: Same as above, except no pre-plant interval.

Turfgrass in Golf courses and Sod farms (*Anquina pacificae* nematode control only): 3 gal/A (1st app) when nematode galls are formed. Single repeat application 5-10 days later. Up to 4 apps within next 60 days. Therefore,

$$3.0 \text{ gal/A/app} \times 9.6 \text{ lbs/gal} \times 0.086 = \mathbf{2.5 \text{ lbs a.i./A/app}} \times 2 \text{ apps} = \mathbf{2.5 \text{ lbs a.i./A/yr}}$$

NOTE: *Anquina pacificae* is found only in California
(<http://plpnemweb.ucdavis.edu/nemaplex/Taxadata/G006S6.htm>)

B. Maximum Use Rates (foliar control/suppression of pathogenic fungi):

Grapes, Strawberries: Up to 4 pts product/A/app. for the first app., followed as needed every 7-10 days. Therefore,

$$0.0625 \text{ gal/A/app} \times 9.6 \text{ lbs/gal} \times 0.086 = \mathbf{0.052 \text{ lbs a.i./A/app}}$$

Assuming a year round growing season (worst case) with applications at 7-day intervals:

$$\begin{aligned} (365 \text{ days/yr}) / (7 \text{ days/app}) &= \text{approx } 52 \text{ app/year} \\ 52 \text{ app/yr} \times 0.052 \text{ lbs a.i./A/app} &= \mathbf{2.7 \text{ lbs a.i./yr}} \end{aligned}$$

Avocado: Up to 4 qts/A every 7 days for up to 6 weeks. Therefore,

$$\begin{aligned} 1 \text{ gal/A/app} \times 9.6 \text{ lbs/gal} \times 0.086 &= \mathbf{0.8 \text{ lbs/A/app}} \\ 1 \text{ gal/A/app} \times 9.6 \text{ lbs/gal} \times 0.086 \times 6 \text{ app/yr} &= \mathbf{5.0 \text{ lbs/A/yr}} \end{aligned}$$

C. Maximum Use Rates (to increase yield and/or root development):

Grapes: Up to 2 qts/A every 7 days for up to 10 wk. Therefore,

$$0.5 \text{ gal/A} \times 9.6 \text{ lbs/gal} \times 0.086 = \mathbf{0.4 \text{ lbs a.i./A/app}} \times 10 \text{ app} = \mathbf{4.1 \text{ lbs a.i./yr}}$$

Citrus: Up to 2 gal/A (1st app), then every 14 days for up to 6 wk. Therefore,

$$2 \text{ gal/A} \times 9.6 \text{ lbs/gal} \times 0.086 = \mathbf{1.7 \text{ lbs a.i./A/app}} \times 3 \text{ app} = \mathbf{5.0 \text{ lbs a.i./yr}}$$

(no foliar exposure on citrus)

Strawberry: Up to 4 pts/A every 14 days for up to 10 wk. Therefore,

$$0.25 \text{ gal/A} \times 9.6 \text{ lbs/gal} \times 0.086 = \mathbf{0.2 \text{ lbs a.i./A/app}} \times 5 \text{ app} = \mathbf{1.0 \text{ lbs a.i./yr}}$$

RISK ASSESSMENT - Human Health

The product (comprised of 8.6% quillaja saponins) is in Toxicity Category III for oral and dermal toxicity, Toxicity Category II for acute inhalation toxicity and primary eye irritation, and Toxicity Category IV for primary dermal irritation; it is not a dermal sensitizer. Quillaja saponins are not genotoxic or mutagens. The active ingredient has no teratogenic effects and are not immunotoxic. They have no subchronic or chronic oral toxicity. When applied according to label directions, there will be no acute, subchronic, or chronic exposure via ocular, dermal, or inhalation routes of exposure when appropriate PPE (Toxicity Category II) is used by applicators/handlers (**including use of goggles and respirators when product is applied using spray equipment**). There are no endocrine effects in humans. Saponins have been demonstrated to have anticarcinogenic properties (Li et al., 2002; Rao and Sung, 1995) and to stimulate the immune system (Kenarova et al., 1990; Wu et al., 1990). Bidesmosidic triterpenoid saponins (such as those present in the active ingredient) are present in many plants used for human food with no reports of adverse effects.

Dietary Exposure to Humans: Dietary exposure is only likely to occur from those crops for which foliar applications of product are intended (grapes and strawberries) to control pathogenic fungi. Average daily intake of quillaja saponins from treated strawberries, grapes, and raisins (processed from grapes) is estimated to be **0.28 mg/kg body wt.** This is well below the established ADI of 5 mg/kg body wt (WHO, 2002). Dietary exposure was estimated using the calculations described below (assuming application only of the 8.6% product):

Label use directions indicate that both commodities can be treated with a maximum of 4 pts product at seven day intervals with no limitation on the number of sprays. Using EPA's Terrestrial Exposure Model (T-Rex V 1.2.3, dated 8/8/2005) and a worst case scenario of one spray application every 7 days for 52 weeks, maximum potential residues of quillaja saponins (upper bound Kenaga value) never exceed 1.26 mg a.i./kg of strawberries or grapes.

For strawberries, annual U.S. consumption has been estimated to be 3.56 lbs (1.62 kg)/person (USDA, 1995). If the strawberry fruit is assumed to have the maximum calculated quillaja residues present, the annual consumption of quillaja saponins from strawberries would be

$$1.26 \text{ mg a.i./kg strawberry} \times 1.62 \text{ kg strawberry/person/year} = \mathbf{2.04 \text{ mg a.i./person/yr;}}$$

for a 70 kg human this is equivalent to **0.03 mg a.i./kg body wt/yr.**

For grapes, annual U.S. consumption of fresh grapes has been estimated to be approximately 8 lbs (3.63 kg)/person (USDA, 2005). If the grapes are assumed to have the maximum

calculated quillaja residues present, the annual consumption of quillaja saponins from grapes would be:

$$1.26 \text{ mg a.i./kg grapes} \times 3.63 \text{ kg grapes/person/year} = \mathbf{4.57 \text{ mg a.i./person/yr;}}$$

for a 70 kg human this is equivalent to **0.07 mg a.i./kg body wt/yr.**

Raisins processed from grapes have an annual per capita consumption of 1.55 lbs (USDA, 1997). If the grapes are assumed to have the maximum calculated quillaja residues present, and a processing factor of 1.66 (FAO, 1997) is applied to the processing of grapes to raisins the annual consumption of quillaja saponins from raisins would be:

$$\begin{aligned} 1.26 \text{ mg a.i./kg grape} \times 1.55 \text{ kg raisin/person/year} \times 1.66 \text{ raisin/grape} \\ = \mathbf{5.79 \text{ mg a.i./person/yr;}} \end{aligned}$$

for a 70 kg human this is equivalent to **0.08 mg a.i./kg body wt/year.** Total estimated dietary exposure to quillaja saponins from strawberries, grapes, and raisins is equal to

$$\mathbf{0.18 \text{ mg a.i./kg body wt/year}}$$

This level is well below the established ADI of 5 mg/kg body wt/day (WHO, 2002).

Bidesmosidic triterpenoid saponins, such as those found in Quillaja extracts, are found in a large number of plants used for human food, flavoring, herbs, and spices (Oakenfull and Sidhu, 1989; Oakenfull, 1981; Lasztity et al., 1998). Up to 100 mg saponin has been measured in a kg of sugar extracted from sugar beets (*Beta vulgaris*) and soybean flour and soybean protein has been shown to contain up to 2.5% saponin (Oakenfull, 1981; Sancho et al., 2000). It has been estimated that saponins comprise the pharmacologically active components of approximately 30% of all medicinal plants (Balandrin, 1996; Liu, 1995). Saponin extracts derived from the bark of the quillaja tree are recognized as FDA GRAS (21 CFR 172.510). Quillaja saponaria (soapbark) is on EPA's List 4A of minimal risk inert ingredients for use in pesticides without restriction. Quillaja extracts are also used as emulsifiers in baked goods, candies, frozen dairy products, gelatin, and puddings (WHO, 2002). It is present in soft drinks at concentrations of up to 200 ppm (EAEMP/CVMP, 1996).

Occupational and Residential Exposure: None. There will be no oral, dermal, and/or inhalation exposure to workers or applicators via proper use of PPE (see Label Review above). The product is not intended for homeowner (residential) use and, therefore, there will be no residential exposure.

Drinking Water: There is insufficient information to assess exposure to Quillaja saponins in drinking water, although it seems highly unlikely that Quillaja saponin levels would exceed what is already intentionally added to commercial soft drinks and beer.

Endocrine Disruption: Based on the weight of evidence, the use of Quillaja saponins in pesticide products will not result in any adverse effects to mammalian and avian endocrine systems. Triterpenoid saponins (such as those present in the active ingredient) are present in many plants used for human food (see review by Oakenfull, 1981) with no reports of adverse effects. Humans are regularly exposed to low levels of triterpenoid saponins (such as those found in quillaja) in food and dermally via intentional and unintentional dermal exposure to ornamental and food plants. Similarly, mammalian wildlife and birds are regularly exposed to saponins in food and feed. Quillaja saponins are widely used as adjuvants in oral and injectable vaccines (Liu et al., 2002; Pickering et al., 2006; Ronnberg et al., 1995).

CONCLUSION: There are no human health concerns when this food use product (containing 8.6% Quillaja saponins) is applied according to label use directions. The data support the petition for an exemption from the requirement of tolerances for Quillaja saponin on food when the product is used at the proposed label rates, methods and use sites.

RISK ASSESSMENT - Non Target Organisms and Endangered Species

General Information: Quillaja saponins are practically non-toxic to birds and fish on an acute and dietary basis, and there have been no reports of adverse effects to plants in efficacy studies using the product as the sole active ingredient. Quillaja saponins are slightly toxic to aquatic invertebrates (Penaeid shrimp). The contact toxicity of Quillaja saponins on non-target insects is unknown.

Environmental Fate

Biodegradation of Saponins: There are no specific data regarding the degradation of quillaja saponins in the environment. In a study conducted by Molgaard et al. (2000), biodegradability of endod (*Phytolacca dodecandra*) berry saponins, a potent molluscicide, was evaluated. The freshwater snail *Biomphalaria glabrata* and red blood cells were used as bioassays to measure saponin potency, in conjunction with an HPLC method to quantitatively assess saponin levels in "clean" water or river water (from the Guruve River in Zimbabwe). Using the hemolysis (red blood cell) bioassay, saponins extracted with water from endod berries (at initial concentrations of 15, 30, 75 and 150 ppm) were observed to be stable for two days, then degraded rapidly between Days 3 and 4 in both clean and river water. In the same aquaria, snail survival in clean water was 0% on Day 0, approximately 40% on Day 4, and 100% on Days 9 to 30; in river water, survival was 0% on Day 0, approximately 60% on Day 4, approximately 80% on Day 9, and 100% on Days 23 to 30. Snail mortality ranged from LC50 = 6.8 to 9.6 ppm. In a second study, HPLC analysis of clean demonstrated similar decreases in saponin concentrations over time, regardless of initial concentration (15, 35, or 75 ppm) and the decreases were in agreement with decreases in saponin potency as measured with the hemolysis assay. In this study, initial saponin concentrations of 15 ppm and 75 ppm declined to non-detectable levels in 5 and 11 days, respectively. A third study using OECD 301 F protocols, demonstrated that endod saponins had a half-life of 15.8 hours in activated sludge.

Birds: There are no concerns for non-target birds, including endangered species. Acute oral LD₅₀ in Bobwhite quail was >2250 mg Quillaja Extract/kg body weight (practically non-toxic), the highest dose tested. The no-mortality level was 1350 mg/kg (the single mortality was likely not treatment-related), and the no-observed-effect level (NOEL) was 292 mg/kg (based on food aversion, erect posture, and/or ruffled appearance).

In a non-guideline dietary study (Jenkins and Atwal, 1994), 1-day old, chicks were fed the equivalent 1000-9000 ppm Quillaja saponin in the diet for 28 days. All chicks survived and gained weight throughout the study. Weight gain was significantly reduced only at the highest dose (9000 ppm) which was associated with reduced food intake. Except for equivocal evidence that absorption of vitamins A and E was reduced, no clinical signs of toxicity were reported for chicks at any dose level. Based on reduced food intake and subsequent weight gain, the LOAEL = 9000 ppm QS and the NOAEL >3000 ppm QS in the diet.

Aside from the studies discussed above, little data are available regarding the toxicity of triterpenoid quillaja saponins to birds. Weight gain and survival of broiler chicks administered a diet consisting solely of raw quinoa (*Chenopodium quinoa*) seed was significantly reduced after 28 days, relative to birds fed wheat, sorghum or maize (Improta and Kellems, 2001). However, the authors attribute low survival rates and low weight gain to result from significantly reduced food consumption caused by food aversion to the saponins in the diet. Conversely, Miah et al. (2004) reported improved growth and meat quality of male broiler chickens fed up to 75 mg of an unidentified saponin in a diet of maize/soybean meal. A mixture of six unidentified saponins extracted from the highly poisonous plant Alfombrilla (*Drymaria arenarioides*) resulted in 100% mortality 4-hrs after being fed to 1-week old chicks at 2% of their body weight (Williams, 1978), although these saponins are unlikely to be the triterpenoid saponins typically found in edible crop plants. An ECOTOX search did not report any Quillaja saponin toxicity data for birds.

Saponins are widely distributed in diverse plant species (see review by Francis et al., 2002). Triterpenoid saponins (such as those present in the active ingredient) are common in cultivated crops (Oakenfull, 1981) including those preyed upon by birds. Therefore, bird dietary exposure to naturally-occurring saponins in plants is likely to be widespread.

Fish: There are no acute or dietary concerns for fish. However, there is limited and equivocal data (Francis et al. 2001 & 2002c) suggesting that Quillaja saponins may be a teratogenic and/or an endocrine disruptor in fish. The first study (Francis et al., 2001), suggests that egg production in Tilapia may be reduced in when fish are exposed to 150-300 ppm of dietary quillaja saponins continuously for 14 weeks. In a second report by the same investigator (Francis et al., 2002c) it was demonstrated that when Nile tilapia fry are exposed to high levels of dietary quillaja saponins (700 ppm) continuously for 8 weeks, there is a shift in the normal 1:1 ratio of males:females towards males. It is uncertain whether the observed effects on fish are actually related to direct effects of quillaja saponins on fish endocrine systems. An extensive literature search, including a search of EPA's ECOTOX database did not reveal any other reports indicating endocrine effects of quillaja saponins, or any other saponin, on fish or on any other taxa. The data on fish reproduction in particular are equivocal in that the study

was not designed as a fish reproduction study and the observations of reduced egg production were serendipitous. There are no other specific data available regarding the toxicity of bidesmoside triterpenoid quillaja saponins to fish, although bidesmosides have been shown to be less toxic than mondesmosides (Duncan, 1985; Hostettman et al., 1982).

Aquatic Invertebrates: Based on a study using Penaeid shrimp, Quillaja saponins are slightly toxic to aquatic invertebrates (48-hr EC₅₀ = 20.83 ppm). Additionally, the same study indicated that subchronic exposure (36 days) of exposure to 0.5 ppm Quillaja saponins reduced growth, feed intake, the time to first molt, and molting frequency. Due to effects of growth and physiology at relatively low concentrations, there are concerns for the effects of Quillaja saponins on growth and physiology of non-target aquatic invertebrates.

Fish And Aquatic Invertebrate Assessment: There is insufficient information regarding the amount of Quillaja saponins that may potentially run-off into aquatic systems via the various label application methods and rates, or as a result of unexpected precipitation events following application, and no information regarding the Estimated Environmental Concentrations (EEC) that may result from this potential run-off. Biotic and abiotic degradation/dissipation rates are also unknown. Proposed repeat applications to soil and foliage, and subsequent run-off, has the potential to increase Quillaja saponin concentrations in aquatic ecosystems to a level that will result adverse effects in fish (endocrine, teratogenic) and other aquatic organisms (affects on growth and physiology).

Based on the observed effects on fish (Nile tilapia) and an aquatic invertebrate (Penaeid shrimp), Biochemical Pesticides Tier II Environmental Fate data requirements are triggered. The registrant is directed to 40 CFR 158.690 (d) Nontarget organism, fate and expression data requirements - Tier II. Protocols for these test Guidelines may be found in OPPTS Harmonized Guidelines Series 835 Fate, Transport and Transformation Guidelines. In lieu of these studies, the registrant must submit a credible rationale, supported with quantitative data, demonstrating that Quillaja saponins, when applied according to proposed label directions, will not run-off into aquatic sites in sufficient quantities to induce potential endocrine and/or teratogenic effects and/or will degrade with sufficient rapidity so as not to cause these effects.

Additionally, since there is insufficient information regarding the potential for run-off following application of the product, the registrant must conduct a Fish Life Cycle toxicity study (OPPTS 850.1500) to alleviate concerns regarding potential teratogenic and/or endocrine effects in fish. Shifts in normal male:female ratios or any other potential teratogenic and/or potential endocrine effects in fish must be reported.

Non-Target Plants: No plant toxicity was observed in any product efficacy trials conducted by the registrant (see MRIDs 466081-11 to -24; & 466310-01) in treatments where Quillaja saponins were the sole active ingredient. Therefore, direct exposure, and indirect exposure to non-target plants via spray drift is not a concern. Furthermore, saponins are widespread in plants and triterpenoid saponins (such as those present in the active ingredient) are common in many cultivated crops (Oakenfull, 1981).

Non-Target Insects: No studies or waiver requests were submitted. Limited available information suggests that saponins are toxic to larval forms of aquatic insects, but not adults (see Review by Francis et al., 2002), due to effects on respiratory membranes.

It is known that the Soapbark tree (*Quillaja saponaria*) from which the active ingredient is derived is attractive to beneficial insects. Green and brown lacewings, which as adults feed on flower nectar, pollen and honeydew; convergent ladybeetle; Syrphid and chloropid flies; and ichneumon, chalcid, and brachonid wasps are abundant on, or attracted to the Soapbark tree (ATTRA, 2006; Bugg, 1990; Earthworks, 2006). A plant that contains bidesmodic triterpenoid saponins similar to those found in *Quillaja saponaria*, the quinoa plant (*Chenopodium quinoa*) is susceptible to attack by many insect pests from seed germination through harvest (Hellin and Higman, 2005; Oelke et al., 1992; Rasmussen et al., 2001 & 2003; Yabar et al., 2002) demonstrating that insects are already widely exposed to bidesmodic triterpenoid saponins and are not adversely affected by the saponin content of the plants when feeding. The product is not intended for direct application to insects or aquatic environments where certain insect species may breed, although aquatic environments may be inadvertently exposed via run-off. The product is applied pre-plant and post plant via ground spray equipment to the soil, low pressure drip, sprinkler, and strip tubing irrigation. It is important to note that it is uncertain what effects direct contact of *Quillaja* saponins (via spray or sprinkler applications) may have on non-target insects. The product is not intended for direct application to insects or aquatic environments where certain insect species may breed, but the potential for contact exposure and contact toxicity via spray and sprinkler applications is unknown.

CONCLUSIONS: There are no concerns for non-target birds, including endangered bird species. There is no apparent toxicity to *Quillaja* saponins when birds are exposed on an acute or dietary basis.

No specific data are available regarding the degradation and/or environmental fate of *Quillaja* saponins in soil or aquatic ecosystems and, therefore, it is difficult to model Estimated Environmental Concentrations (EEC) in soil and aquatic ecosystems, as well as in drinking water, that is potentially exposed to run-off. Since it is unclear whether *Quillaja* saponins will move into aquatic environments at high enough concentrations to adversely affect aquatic organisms, or remain in the environment for a time sufficient to adversely affect aquatic organisms, certain Biochemical Pesticides Tier II Environmental Fate data will be required.

In addition, there are no data available regarding the contact toxicity of *Quillaja* saponins to non-target insects. These data are required. In the absence of these contact toxicity data, *Quillaja* saponins must be assumed to be toxic to non-target insects.

Based on the lack of reliable data, potential exposure and toxicity to non-target and endangered fish, aquatic invertebrates, and insects cannot be assessed at this time.

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cc: R. S. Jones, D. Benmhend, BPPD Subject File/IHAD
R. S. Jones: Sr. Biologist, F.T. 1PY, (703) 308-5071: 07/28/2006

MATERIAL TO BE ADDED TO JACKET

REG #

82572-1

Description:

materials missing from jacket, label,
CSF, note to file, correspondence

if applicable, check all that are attached		Send to CSC
<input checked="" type="checkbox"/>	new stamped accepted label	
<input checked="" type="checkbox"/>	new CSF	
<input type="checkbox"/>	notification	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer's
Name:

Fournier, John

Date:

2/9/09
~~1/27/09~~

Phone:

703.308.0169

Division:

BPPD

NOTE TO FILE

3 February, 2009

Registration # 82572-1

Quillaja Extract

On 2 February, 2009, the Agency approved an application to amend the registration above. The registrant modified their manufacturing process, substituting [REDACTED] resulting in lower eye irritation. This supported the registrant's request to lower the signal word from Danger to Warning.

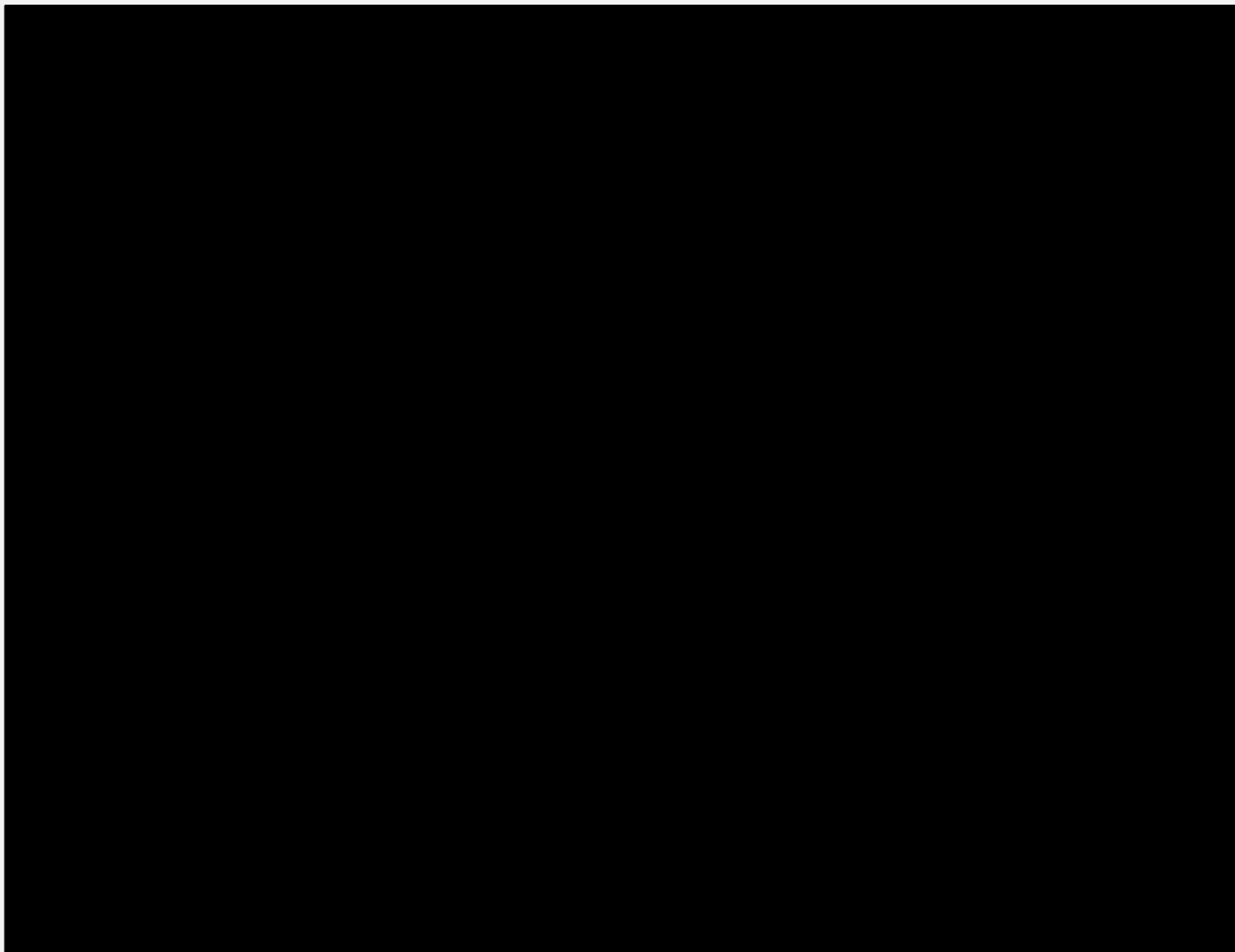
Upon review of the submitted application, it was found that the registrant had failed to update their manufacturing process and CSF to indicate [REDACTED]. I requested that the registrant make minor corrections and submit the documents to me. They submitted a corrected CSF, dated January 22, 2009 and a corrected page 12 of manufacturing process, both of which were reviewed and accepted.

Although the manufacturing process has been corrected, reviewed, and accepted, the registrant still needs to re-submit the complete corrected version of their manufacturing process (not just page 12) so that it will be assigned an MRID and become part of the electronic record. I have requested today that they submit the manufacturing process back through our Front End Processing.



John Fournier, BPB

Re: MRID 475423-01



FEB 02 2009

Heather R. Bjornson, Regulatory Agent
Technology Sciences Group, Inc.
1150 18th Street, N.W. Ste. 1000
Washington, DC 20036

Subject: Quillaja Extract
EPA Registration No. 82572-1
Label and CSF Amendment
Application Dated September 15, 2008

Dear Ms. Bjornson:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5), is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit three (3) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(b). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions contact John Fournier at 703-308-0169 or by email at: fournier.john@epa.gov. A stamped copy of the label is enclosed for your records.

Sincerely,



Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures

Concurrence:

7511 P

Fournier

27 Jan 09



Quillaja Extract

A Bio-Pesticide



*For Control of Plant Parasitic Nematodes and Plant Parasitic Fungi
in Vineyards, Orchards, Field Crops, Turf and Ornamentals*

Active Ingredient:

*Saponins of Quillaja saponaria 8.60%

Other Ingredients 91.40%

Total 100.00%

*bidesmosidic derivatives of quillajic acid substituted with a trisaccharide at C-3 and an oligosaccharide in C-28

KEEP OUT OF REACH OF CHILDREN

WARNING - ADVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

See back side for additional precautionary statements

Manufactured for:
Desert King Chile
77 Antonio Bellet, Suite 401
Providencia, Santiago
Chile

EPA Reg. No.: 82572-1
EPA Est. No.: XXXXX-XX-XX

Net Contents: XX Gallons
Batch Code: XXX

ACCEPTED

FEB 02 2009

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 82572-1

Desert King – Quillaja Extract: EPA Reg. No. 82572-1
Label Version (7); September 15, 2008

Page 1 of 13

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye damage. Do not get in eyes or on clothing. Harmful if swallowed or absorbed through skin. Avoid contact with skin.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Protective eyewear
- Chemical-resistant gloves made of any waterproof material
- Shoes and socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Never apply material so as to contaminate eating or drinking area.
- Remove clothing/PPE immediately if product gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the Agency responsible for pesticide regulations.

ACCEPTED

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label about personal protective equipment and the restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard. Do not enter or allow worker entry into treated areas without protective clothing during the restricted-entry interval (REI) of 24 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Chemical-resistant gloves made of any waterproof material
- Protective eyewear
- Shoes and socks

NON - AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of the product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural and ornamental plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

Mixing:

Fill tank with water to at least half full, then add recommended dosage of Quillaja Extract directly to the tank and continue filling. Agitation should be minimized in the tank (shut off paddle agitation if possible) to prevent foaming. To reduce foaming, an agricultural defoamer may be added to the tank mix. However, Quillaja Extract foam is very water soluble, will form a true solution, and should not be a concern for settling in the tank. Apply solution within three hours of mixing.

Compatibility:

Quillaja Extract is a water soluble botanical extract. It is physically compatible with most water based pesticides and liquid fertilizers providing the pH of the final solution is in a pH range of 3 to 8. Do not apply Quillaja Extract with any other product before testing for physical and chemical compatibility. To determine compatibility, pour the recommended proportions of the products into a suitable container, mix and wait for 30 minutes. If product remains mixed, it is considered physically compatible.

Not all tank mix combinations have been tested with this product. If compatibility of this product with another product is unknown, the mixture should be tested on a small scale.

Read and carefully observe the most restrictive of the labeling limitations and precautions of all product labels used in the tank mix. This product has properties similar to wetting agents and may enhance activity of some products as a wetting agent.

Application Methods: Consider the high solubility of this product when choosing a method of application and timing.

Foliar spray application (for powdery mildew): Apply by ground equipment to ensure complete and thorough coverage of foliage and/or crop. Contact of the disease organisms is essential for curative control.

Ground spray application (for nematodes and root rot): After area to be treated has been irrigated to field capacity, apply with a band or broadcast type sprayer, such as flat-fan or hollow cone nozzle tip system, to the soil surface. After application has been made it will be necessary to water with either drip, above ground sprinklers or reduced amount of furrow irrigation. Do not over irrigate following application of this product. Do not use flood irrigation to apply this product into the ground. Over irrigation will move the desired concentration of the product too quickly past the targeted root zone.

For ground sprayer application in orchards or around trees, begin application next to the tree trunk and spray at least 50% of soil area or the area under the canopy of the tree, whichever is greatest.

Shank injection application (for nematodes): After area to be treated has been irrigated to field capacity, apply by shank injection to areas where roots are present. Use a sufficient number of injectors to cover area to be treated. If shank application is applied at the root zone, minimal irrigation is required to assure that product covers root zone.

Chemigation application (for nematodes and root rot): Apply Quillaja Extract through the following types of systems. Do not apply this product through any other type of irrigation system.

- Low volume (ground or underground) drip, drip tape, strip tubing, micro-jet sprinklers, mini-sprinklers;
- Sprinkler including center pivot, lateral move, end tow, side (wheel) roll, solid set, or hand move;
- Furrow.

Check irrigation system and emitters to ensure all systems are operating normally before injecting Quillaja Extract. Lack of effectiveness or crop injury can result from non-uniform distribution of treated water.

If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers, chemigation experts or the Distributor of this product.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place. In addition, check local and state regulations regarding pesticide injection into public water systems.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Maintain the system's operating pressure low enough to prevent fogging and/or misting during applications. Inject Quillaja Extract into the irrigation system after the filter(s) or shut off the automatic back flush system in order to avoid back flushing of treated water.

Systems using a gravity flow pesticide dispensing system must meter the product into the water at the head of the field and downstream of the hydraulic discontinuity, such as

a drop structure or well box, to decrease potential for water source contamination from backflow if water flow stops.

Systems using a pressurized water and pesticide injection system must meet the following requirements:

- The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
- The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of material that are compatible with pesticide and capable of being fitted with a system interlock.

It is highly recommended that the soil be irrigated to field capacity (down to two feet of soil) before pesticide application. For best results, inject Quillaja Extract into the irrigation line in the last quarter of the irrigation time. Continue irrigation until all lines are flushed. Maintain irrigation for enough time to assure this product has penetrated down into the targeted root zone. Do not over irrigate after applying this product. If excessive watering occurs immediately following application, this product may move down past the desired root zone due to its high water solubility. Do not irrigate for at least 24 hours following application of this product. Pest injury to the crop or lack of effectiveness in growth response may result from uneven distribution of this product during application.

Do not allow air in the line prior to injecting Quillaja Extract. The product's density will cause swelling of the line due to foam formation and prevent uptake of material. If a pesticide supply tank is used, follow directions listed under "Mixing" above. There generally will be some level of foam at the base of the wetted area until it dissolves (usually within 30 minutes after application, depending on temperature and amount of water following application).

If applied in heavy rainfall areas, avoid application during rain or when rain is forecasted within the next 24 hours that may exceed movement of this product past targeted root zone.

Do not apply when wind speed favors drift beyond the areas intended for treatment

Application Rates for Control of Nematodes

To control/suppress plant parasitic nematodes, apply Quillaja Extract to the full irrigated zone. For row crops, the irrigated zone is 30-50% of the row area. For orchards or around trees, apply from tree trunk to drip-line to cover at least 50% of soil area or the area under the canopy of the tree, whichever is greatest. Single applications should be made in the spring just prior to or during root flush, and again in the fall after harvest. For best results, multiple applications may be made in the spring, followed by a single application in the fall after harvest.

Crop	Remarks
Berries: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Huckleberry, Loganberry, Raspberry (black and red)	On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.
Citrus: Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo	On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.
Grapes (raisin, table, wine)	For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.
Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)	
Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince	
Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune	

Cole Crops:

Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables:

Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables:

Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables:

Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Strawberry

Apply 1-7 days preplant to the planting zone. Apply centered on the top of the row on pre-wetted soil. Follow with water to assure penetration of the product into the root zone.

On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.

On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.

For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.

<p>Bulb Vegetable: Garlic, Leek, Onion (including dry bulb, green and Welch), Shallot</p> <p>Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Ginseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)</p> <p>Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals</p>	<p>Apply prior to planting to row area to be planted. Apply centered on the top of the row on pre-wetted soil. Follow with water to assure penetration of the product into the root zone.</p> <p>On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.</p>
<p>Turfgrass Ornamental lawns, Golf courses, Sod farms</p> <p>For control of <i>Anguina pacifica</i> nematode only.</p>	<p>Apply 9 fl.oz. in 3-7 gallons water per 1,000 sq.ft. (equivalent to 3 gallons in 130-300 gallons water per acre) using a sprayer with a pressure nozzle tip applicator sufficient to penetrate into the lower part of the turf leaves where <i>Anguina pacifica</i> nematode galls are formed. Do not exceed a concentration of 1.5% solution of Quillaja Extract in any application.</p> <p>Repeat applications every 5-10 days. Additional applications to break the life cycle of the nematode should be repeated 2-4 times within 60 days to significantly reduce this pest problem in one season.</p> <p>Do not water turfgrass for at least 12 hours following application of Quillaja Extract. Quillaja Extract is water soluble and does not require additional water application through sprinkler following application.</p>

Application Rates for Control of Fungi

For control/suppression of **POWDERY MILDEW** in the following field and greenhouse-grown crops, apply 1-4 pints Quillaja Extract per acre as a foliar spray in 50-100 gallons

Desert King – Quillaja Extract: EPA Reg. No. 82572-1
Label Version (7); September 15, 2008
Page 8 of 13

water per acre (equivalent to 0.5-1.5 fl.oz. in 1-2 gallons water per 1,000 sq.ft.) every 7-10 days depending on severity of infection. A surfactant is not necessary, but the addition of a wetting agent, such as Yucca Ag-Aide™, may increase efficacy. Quillaja Extract may be tank mixed with Sterol Inhibitor type fungicides.

Berries and Small Fruits: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Grape (raisin, table, wine), Huckleberry, Kiwifruit, Loganberry, Raspberry (black and red), Strawberry

Bulb Vegetable: Garlic, Leek, Onion (including dry bulb, green and Welsh), Shallot

Cereal Grains: Barley, Buckwheat, Corn, Millet, (pearl and proso), Oats, Popcorn, Rice, Rye, Sorghum (milo), Teosinte, Triticale, Wheat, Wild rice

Cole Crops: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables: Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Legume Vegetables (succulent or dried): Bean (*Lupinus*, *Phaseolus* and *Vigna* spp.), Broad bean, Chickpea, Guar, Jackbean, Lablab bean, Lentil, Pea (*Pisum* spp.), Pigeon pea, Soybean, Sword bean

Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)

Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince

Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Gingseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune

Subtropical Fruits: Banana, Date, Mango, Papaya, Pineapple

Additional crops: Hops, Mint (peppermint, spearmint), Tobacco

Herbs and Spices: Allspice, Angelica, Anise, Annatto, Balm, Basil, Borage, Burnet, Camomile, Caper buds, Caraway, Cardamom, Cassia, Catnip, Celery seed, Chervil, Chive, Cinnamon, Clary, Clove buds, Coriander, Coriander,

Costmary, Culantro, Cumin, Curry, Dill, Fennel, Fenugreek, Grains of paradise, Horehound, Hyssop, Juniper berry, Lavender, Lemongrass, Lovage, Mace, Marigold, Marjoram, Mustard, Nasturtium, Nutmeg, Parsley, Pennyroyal, Pepper, Poppy seed, Rosemary, Rue, Saffron, Sage, Savory, Sweet bay, Tansy, Tarragon, Thyme, Vanilla, Wintergreen, Woodruff, Wormwood

Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals

Turf: Ornamental lawns, golf courses and sod farms

For control/suppression of **PHYTOPHTHORA** and **PYTHIUM ROOT ROT** in the following field and greenhouse-grown crops, apply 2-4 quarts Quillaja Extract in 200 gallons water per acre (equivalent to 1.5-3 fl.oz. in 5 gallons water per 1,000 sq.ft.) to achieve a concentration of 2,500-5,000 ppm. Apply in early spring and fall, prior to root flush when soil temperatures are optimum for root infection. Apply to the entire root zone following, or at the end of, an irrigation cycle For best results, repeat application every 7 days, for up to 6 weeks. A surfactant is not necessary, but the addition of a wetting agent, such as Yucca Ag-Aide™, may increase efficacy. Quillaja Extract may be tank mixed with Sterol Inhibitor type fungicides.

Berries and Small Fruits: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Grape (raisin, table, wine), Huckleberry, Kiwifruit, Loganberry, Raspberry (black and red), Strawberry

Citrus: Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo,

Cole Crops: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables: Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)

Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince

Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Gingseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune

Additional crops: Avocado, Kiwifruit

Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals

Application Rates to Enhance Plant Growth and Yield

Under good growing conditions, absent of plant parasitic nematodes or plant parasitic fungi, Quillaja Extract is beneficial to plant growth and yield as described below.

Crop	Benefit	Rate per Acre	Comment
Grapes	Increased Fruit Yield and Root Development	1-2 quarts	Apply at root flush followed by 2-4 applications at 7-14 day intervals.
Citrus	Increased Root Development	1-2 gallons	Apply at root flush followed by 2 quarts/acre every 14 days for 4-6 weeks.
Strawberry	Increased Root Development	2-4 pts	Apply every 14 days for 8-10 weeks.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in cool dry area.

Pesticide Disposal: Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Un-Refillable Container. Do not refill or reuse this container. Triple rinse (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

LIMITED WARRANTY

Desert King Chile warrants that this product conforms to the chemical description on the label and is reasonable fit for the purposes set forth in the Complete Directions for Use label booklet ("Directions") when used in accordance with those Directions under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MECHANABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

[] indicate optional text

Optional Label Claims:

- Controls and/or Suppresses certain foliar diseases such as Powdery Mildew(s)
- Suppresses [Nematodes], [Powdery Mildew]
- For use also on Vegetable Crops Such as: Carrots, Peppers, Tomatoes, Broccoli, Squash, and Beets.



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: Januray 26, 2009

SUBJECT: Science Review in Support of the Registration of Quillaja Extract, Containing 8.6% Quillaja Saponaria, Extract As Its Active Ingredient.

Decision Number:	400157
DP Number:	357325
EPA File Symbol Number:	82572-1
Chemical Class:	Biochemical
PC Code:	097095
CAS Number:	68990-67-0
Tolerance Exemptions:	40 CFR 180.1278
MRID Numbers:	47542301, 47542302, 47542303

FROM: Jacob Moore, Chemist /s/ 01/26/09 *[Signature]*
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THROUGH : Russell S. Jones, Ph.D. Senior Biologist /s/ 01/26/09 *[Signature]*
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: John Fournier, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THE FOLLOWING CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED

In response to the request for additional information discussed in a memorandum from Jacob Moore to John Fournier dated 12/22/08 the registrant has submitted a confidential statement of formula dated 01/26/09.

RECOMMENDATIONS AND CONCLUSIONS

1. CSF dated 01/22/09 is acceptable.
2. The revised formulation process (OPPTS Guideline 830.1620) is acceptable.
3. The resubmitted formulation process is acceptable. The primary eye irritation studies (OPPTS Guideline 870.2400) are acceptable. The Toxicity Category is II.

Product Chemistry

The registrant has submitted a revised formulation process for Quillaja Extract (a.i. 8.6% Quillaja saponins). The formulation process has been modified by [REDACTED]

[REDACTED] as noted in the formulation process and on the CSF dated 01/22/09. The resubmitted formulation process is acceptable.

Toxicity

The Acute Eye Irritation – Rabbits (OPPTS 870.2400) study was completed twice. Corneal opacity was noted on three of three rabbits one hour through 7 days after test material instillation with resolution by day 14. Iritis was noted on three of three rabbits one through 24 hours after test material instillation with resolution by day 14. Positive conjunctival irritation (score 2 of 3) was noted on three of three rabbits one hour after test material instillation with resolution by day 14. The maximum average scores for the two tests were 57.0 and 58.3 at one hour after test material instillation. Quillaja Extract was extremely irritating. The acute eye irritation data warrants a toxicity category II for Quillaja Extract.

cc: J. Moore, R. Jones, J. Fournier, BPPD Science Review File, IHAD/ARS
J. Moore, FT, PY-S: 01/26/09



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: December 22, 2008

SUBJECT: Science Review in Support of the Registration of Quillaja Extract, Containing 8.6% Quillaja Saponaria, Extract As Its Active Ingredient.

Decision Number:	400157
DP Number:	357325
EPA File Symbol Number:	82572-1
Chemical Class:	Biochemical
PC Code:	097095
CAS Number:	68990-67-0
Tolerance Exemptions:	40 CFR 180.1278
MRID Numbers:	47542301, 47542302, 47542303

FROM: Jacob Moore, Chemist /s/ 12/22/08 *Jacob Moore*
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THROUGH : Russell S. Jones, Ph.D. Senior Biologist *Russell S. Jones*
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: John Fournier, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THE FOLLOWING CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED

Desert King Chile requests label amendment of Quillaja Extract, which is intended for control of plant parasitic nematodes and plant parasitic fungi in vineyards, orchards, field crops, turf, and ornamentals. In support of this registration, the registrant has submitted revised, draft label, formulation process in MRID 47542301, and eye irritation studies in MRIDs 47542302 and 47542303.

RECOMMENDATIONS AND CONCLUSIONS

1. The CSF is unacceptable, but upgradable upon resolution of the following:
 - a. The amount of active ingredient listed on the CSF must match the amount specified on the label.
2. The revised formulation process (OPPTS Guideline 830.1620) is acceptable.
3. The primary eye irritation studies (OPPTS Guideline 870.2400) are acceptable. The Toxicity Category is II.

Product Chemistry

The registrant has submitted a revised formulation process for Quillaja Extract (a.i. 8.6% Quillaja saponins). The formulation process has been modified by [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The resubmitted formulation process is acceptable.

Toxicity

The Acute Eye Irritation – Rabbits (OPPTS 870.2400) study was completed twice. Corneal opacity was noted on three of three rabbits one hour through 7 days after test material instillation with resolution by day 14. Iritis was noted on three of three rabbits one through 24 hours after test material instillation with resolution by day 14. Positive conjunctival irritation (score 2 of 3) was noted on three of three rabbits one hour after test material instillation with resolution by day 14. The maximum average scores for the two tests were 57.0 and 58.3 at one hour after test material instillation. Quillaja Extract was extremely irritating. The acute eye irritation data warrants a toxicity category II for Quillaja Extract.

cc: J. Moore, R. Jones, J. Fournier BPPD Chron File, IHAD/ARS
J. Moore, FT, PY-S: 12/22/08

DATA EVALUATION RECORD

QUILLAJA SAPONINS (Quillaja Extract)

STUDY TYPES: Description of the Formulation Process (OPPTS 830.1620)

MRID 47542301

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 08-048

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: _____
Date: _____

Secondary Reviewers:
Sylvia Milanez, Ph.D., D.A.B.T.

Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

EPA Secondary Reviewer:

STUDY TYPE:	Description of Formulation Process (OPPTS 830.1620)
MRID NOS:	47542301
DECISION NO:	400157
DP BARCODE:	DP357325
TEST MATERIAL:	Quillaja Extract (a.i., 8.6%% Quillaja saponins)
PROJECT STUDY NO:	QE-2008-1
SPONSOR:	Desert King Chile, Ltd., Antonio Bellet 77 of 401, Providencia, Santiago, Chile
TESTING FACILITY:	Not applicable
TITLE OF REPORT:	Quillaja Extract Product Properties – Group A. Amended.
AUTHORS:	Brookman, D.J. and K.K. Curry
STUDY COMPLETED:	February 20, 2008
CONFIDENTIALITY CLAIMS:	Confidential material is contained in a confidential appendix.
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was included. The study is descriptive only, and is not subject to 40 CFR Part 160.
CONCLUSION:	The registrant has submitted a revised formulation process for Quillaja Extract (a.i., 8.6% Quillaja saponins), EPA Reg. No. 82572-1. The formulation process has been modified by [REDACTED] [REDACTED] [REDACTED] This is the only step in the original formulation process that has been modified.
CLASSIFICATION:	Acceptable

Test Material: Quillaja Extract (a.i., 8.6%% Quillaja saponins), EPA Reg. No. 82572-1

I. **DESCRIPTION OF THE FORMULATION PROCESS:** The registrant has submitted a revised formulation process for Quillaja Extract, EPA Reg. No. 82572-1. During the formulation process, [REDACTED]

[illegible]

[REDACTED]

[REDACTED]
[REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED]
[REDACTED] [REDACTED]
[REDACTED]
[REDACTED] [REDACTED]
[REDACTED]

The original and revised process diagrams are provided on pages 8 and 9 of MRID 47542301, respectively.

Deficiencies: None.

II. ADDITIONAL REVIEWER'S COMMENTS: None.

DATA EVALUATION RECORD

QUILLAJA EXTRACT

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT (870.2400)
MRID 47542302

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 98-048

Primary Reviewer:
Susan Chang, M.S.

Signature: _____
Date: _____

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Acute Eye Irritation - Rabbits (OPPTS 870.2400)
MRID NO:	47542302
DP BARCODE NO:	DP 357325
CASE NO:	Not reported
DECISION NO:	400157
TEST MATERIAL:	Quillaja Extract (EPA Reg. No. 82572-1)
PROJECT NO:	BIBR 6-9146
SPONSOR:	Desert King Chile, Ltd., Antonio Bellet 77 of 401, Providencia, Santiago, Chile
TESTING FACILITY:	Microquim S.A., Av. Riunvirato 3447 (1427) Buenos Aires, Argentina
TITLE OF REPORT:	Quillaja Extract - Primary Eye Irritation
AUTHOR:	Natalia Lope
STUDY COMPLETED:	September 21, 2007
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	Corneal opacity was noted on 3/3 rabbits one hour through 7 days after test material instillation with resolution by day 14. Iritis was noted on 3/3 rabbits one through 72 hours after test material instillation with resolution by day 7. Positive conjunctival irritation (score 2 or 3) was noted on 3/3 rabbits one hour after test material instillation with resolution on two rabbits by day 7 and on the other rabbit by day 14. The maximum average score was 57.0 at one and 24 hours after test material instillation. Quillaja Extract was extremely irritating.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY II

I. STUDY DESIGN:

1. **Test Material:** Quillaja Extract
2. **Test Animals:** Three male young adult New Zealand White rabbits were received from DIPAGA Rabbit House, Ruta 8, Km 94, 2764 Solís, San Andrés de Giles, Buenos Aires, Argentina. The young adult animals were housed individually in steel cages. The animals were fed Ganave, Balanced food for rabbits. Tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, $22\pm 3^{\circ}\text{C}$; relative humidity, 30-70%; air changes, 10-15 per hour; and photoperiod 12 hour light/dark cycle.
3. **Methods:** Rabbits were identified by cage number and picric acid color body marking: Nos. 439, 440, and 441. The rabbits were acclimated for 5 days. The test material (0.1 mL/eye/animal) was applied in the conjunctival sac of one eye, and the eye held closed for approximately one second. The untreated eye served as control. The eyes were washed at 24 hours following instillation of the test material. The eyes were examined and scored 1, 24, 48 and 72 hours and at 7 and 14 days after test material instillation.

II. RESULTS:

1. **Mortality:** All rabbits survived the study.
2. **Ocular Lesions:** Corneal opacity was noted on 3/3 rabbits one hour through 7 days after test material instillation with resolution by day 14 (Table 1). Iritis was noted on 3/3 rabbits one through 72 hours after test material instillation with resolution by day 7 (Table 2). Positive conjunctival irritation (score 2 or 3) was noted on 3/3 rabbits one hour after test material instillation with resolution on two rabbits by day 7 and on the other rabbit by day 14. The maximum average score was 57.0 at one and 24 hours after test material instillation (Table 3).

TABLE 1. Individual Male (M) Eye Scores w/ Time: Cornea (A=Density of Opacity, B=Area of Opacity)												
Animal No.	1 hour		24 hours		48 hours		72 hours		7 days		14 days	
	A	B	A	B	A	B	A	B	A	B	A	B
439	2	-	2	-	2	-	2	-	2	-	0	-
440	2	-	2	-	2	-	2	-	2	-	0	-
441	2	-	2	-	2	-	2	-	1	-	0	-

Irritation score is based on Draize Method

TABLE 2. Summary of Eye Irritation Scores with Time: Conjunctiva and Iris						
Score Conditions	1 hour	24 hours	48 hours	72 hours	7 days	14 days
Conjunctiva						
Erythema	3	3	2 to 3	2	1 to 2	0
Chemosis	3	3	3	2	1	0
Discharge	-	-	-	-	-	-
Iris	1	1	1	1	0	0

Irritation score is based on Draize Method

Grades for Ocular Lesions

Cornea

Opacity: degree of density (area most dense taken for reading)

- No ulceration or opacity 0
- Scattered or diffuse areas of opacity (other than slight dulling of normal luster; details of iris clearly visible) 1*
- Easily discernible translucent areas, details of iris slightly obscured 2*
- Opalescent area, no details of iris visible; size of pupil barely discernible 3*
- Opaque cornea, iris not discernible through the opacity 4*

Iris

- Normal 0
- Marked deepened rugae; congestion; swelling; moderate circumcorneal hyperemia, or injection;
- Any of these or combination of any thereof, iris still reactive to light (sluggish reaction is positive) 1*
- No reaction to light, hemorrhage, gross destruction (any or all of these) 2*

Conjunctivae

Redness (refers to palpebral and bulbar conjunctivae, excluding cornea and iris)

- Blood vessel normal 0
- Some blood vessels definitely hyperemic (injected) 1
- Diffuse, crimson color; individual vessels not easily discernible 2*
- Diffuse, beefy red 3*

Chemosis: Swelling (refers to lids and/or nictitating membranes)

- No swelling 0
- Any swelling above normal (includes nictitating membranes) 1
- Obvious swelling with partial eversion of lids 2*
- Swelling with lids about half closed 3*
- Swelling with lids more than half closed 4*

* indicates positive grades

TABLE 3. Summary of Total ^a and Primary Eye Irritation Scores with Time						
	1 hour	24 hours	48 hours	72 hours	7 days	14 days
439	57	57	57	53	51	0
440	57	57	55	53	44	0
441	57	57	55	53	24	0
Average scores ^b	57.0	57.0	55.7	53.0	39.7	0.0

Calculated by the reviewer, assuming that the area of opacity is 4 and no discharge

^aFormula: Total Irritation Score = I + II + III, where,

I = Corneal Score = [Density (A) x Area (E)] x 5

II = Iris Score = Severity x 5

III = Conjunctival Score = [Erythema (A) + Chemosis (B) + Discharge (C)] x 2

^bAverage Primary Irritation = Sum of Total Irritation Scores ÷ 3

III. DISCUSSION:

Corneal opacity was noted on 3/3 rabbits at one hour through 7 days after test material instillation with resolution by day 14. Iritis was noted on 3/3 rabbits one through 72 hours after test material instillation with resolution by day 7. Positive conjunctival irritation (score 2 or 3) was noted on 3/3 rabbits one hour after test material instillation with resolution on two rabbits by day 7 and on the other rabbit by day 14. The maximum average score was 57.0 at one and 24 hours after test material instillation. Quillaja Extract was extremely irritating and is in TOXICITY CATEGORY II. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

QUILLAJA EXTRACT

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT (870.2400)
MRID 47542303

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 98-948

Primary Reviewer:

Susan Chang, M.S.

Signature: _____

Date: _____

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: _____

Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____

Date: _____

Quality Assurance:

Lee Ann Wilson, M.A.

Signature: _____

Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DF-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Acute Eye Irritation - Rabbits (OPPTS 870.2400)
MRID NO:	47542303
DP BARCODE NO:	DP 357325
CASE NO:	Not reported
DECISION NO:	400157
TEST MATERIAL:	Quillaja Extract (EPA Reg. No. 82572-1)
PROJECT NO:	BIBR 6-9147
SPONSOR:	Desert King Chile, Ltd., Antonio Bellet 77 of 401, Providencia, Santiago, Chile
TESTING FACILITY:	Microquim S.A., Av. Riunvirato 3447 (1427) Buenos Aires, Argentina
TITLE OF REPORT:	Quillaja Extract - Primary Eye Irritation
AUTHOR:	Natalia Lope
STUDY COMPLETED:	September 21, 2007
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	Corneal opacity was noted on 3/3 rabbits one hour through 7 days after test material instillation with resolution by day 14. Iritis was noted on 3/3 rabbits one through 24 hours after test material instillation with resolution on two rabbits by 48 hours and on one rabbit by day 14. Positive conjunctival irritation (score 2 or 3) was noted on 3/3 rabbits one hour through day 7 after test material instillation with resolution by day 14. The maximum average score was 58.3 at one hour after test material instillation. Quillaja Extract was extremely irritating.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY II

I. STUDY DESIGN:

1. **Test Material:** Quillaja Extract
2. **Test Animals:** Three male young adult New Zealand White rabbits were received from DIPAGA Rabbit House, Ruta 8, Km 94, 2764 Solís, San Andrés de Giles, Buenos Aires, Argentina. The young adult animals were housed individually in steel cages. The animals were fed Ganave, Balanced food for rabbits. Tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, $22\pm 3^{\circ}\text{C}$; relative humidity, 30-70%; air changes, 10-15 per hour; and photoperiod 12 hour light/dark cycle.
3. **Methods:** Rabbits were identified by cage number and picric acid color body marking: Nos. 490, 491, and 492. The rabbits were acclimated for 5 days. The test material (0.1 mL/eye/animal) was applied in the conjunctival sac of one eye, and the eye held closed for approximately one second. The untreated eye served as control. The eyes were examined and scored 1, 24, 48 and 72 hours and at 7 and 14 days after test material instillation.

II. RESULTS:

1. **Mortality:** All rabbits survived the study.
2. **Ocular Lesions:** Corneal opacity was noted on 3/3 rabbits one hour through 7 days after test material instillation with resolution by day 14 (Table 1). Iritis was noted on 3/3 rabbits one through 24 hours after test material instillation with resolution on two rabbits by 48 hours and on one rabbit by day 14 (Table 2). Positive conjunctival irritation (score 2 or 3) was noted on 3/3 rabbits one hour through day 7 after test material instillation with resolution by day 14. The maximum average score was 58.3 at one hour after test material instillation (Table 3).

TABLE 1. Individual Male (M) Eye Scores w/ Time: Cornea (A=Density of Opacity, B=Area of Opacity)												
Animal No.	1 hour		24 hours		48 hours		72 hours		7 days		14 days	
	A	B	A	B	A	B	A	B	A	B	A	B
490	2	-	2	-	2	-	1	-	1	-	0	-
491	2	-	2	-	2	-	2	-	2	-	0	-
492	2	-	2	-	2	-	2	-	1	-	0	-

Irritation score is based on Draize Method

TABLE 2. Summary of Eye Irritation Scores with Time: Conjunctiva and Iris						
Score Conditions	1 hour	24 hours	48 hours	72 hours	7 days	14 days
Conjunctiva						
Erythema	2	2	2	2	1 to 2	0
Chemosis	3	3	2 to 3	3	2	0
Discharge	-	-	-	-	-	-
Iris	1 to 2	1	0 to 1	0 to 1	0 to 1	0

Irritation score is based on Draize Method

Grades for Ocular Lesions

Cornea

Opacity: degree of density (area most dense taken for reading)

- No ulceration or opacity 0
- Scattered or diffuse areas of opacity (other than slight dulling of normal luster; details of iris clearly visible) 1*
- Easily discernible translucent areas; details of iris slightly obscured 2*
- Opalescent area, no details of iris visible; size of pupil barely discernible 3*
- Opaque cornea, iris not discernible through the opacity 4*

Iris

- Normal** 0
- Marked deepened rugae; congestion; swelling; moderate circumcorneal hyperemia, or injection;
- Any of these or combination of any thereof, iris still reactive to light (sluggish reaction is positive) 1*
- No reaction to light, hemorrhage gross destruction (any or all of these) 2*

Conjunctivae

Redness (refers to palpebral and bulbar conjunctivae, excluding cornea and iris)

- Blood vessel normal 0
- Some blood vessels definitely hyperemic (injected) 1
- Diffuse, crimson color; individual vessels not easily discernible 2*
- Diffuse, beefy red 3*

Chemosis: Swelling (refers to lids and/or nictitating membranes)

- No swelling 0
- Any swelling above normal (includes nictitating membranes) 1
- Obvious swelling with partial eversion of lids 2*
- Swelling with lids about half closed 3*
- Swelling with lids more than half closed 4*

* indicates positive grades

TABLE 3. Summary of Total ^a and Primary Eye Irritation Scores with Time						
	1 hour	24 hours	48 hours	72 hours	7 days	14 days
490	60	55	55	35	33	0
491	60	55	50	50	46	0
492	55	55	48	50	26	0
Average scores ^b	58.3	55.0	51.0	45.0	35.0	0.0

Calculated by the reviewer, assuming that the area of opacity is 4 and no discharge

^aFormula: Total Irritation Score = I + II + III, where,

I = Corneal Score = [Density (A) x Area (B)] x 5

II = Iris Score = Severity x 5

III = Conjunctival Score = [Erythema (A) + Chemosis (B) + Discharge (C)] x 2

^bAverage Primary Irritation = Sum of Total Irritation Scores ÷ 3

III. DISCUSSION:

Corneal opacity was noted on 3/3 rabbits at one hour through 7 days after test material instillation with resolution by day 14. Iritis was noted on 3/3 rabbits one through 24 hours after test material instillation with resolution on two rabbits by 48 hours and on one rabbit by day 14. Positive conjunctival irritation (score 2 or 3) was noted on 3/3 rabbits one hour through day 7 after test material instillation with resolution by day 14. The maximum average score was 58.3 at one hour after test material instillation. Quillaja Extract was extremely irritating and is in TOXICITY CATEGORY II. The packet classification is **ACCEPTABLE**.



WASHINGTON

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Linda Hollis

September 15, 2008

Chief, Biopesticide and Pollution Prevention Division

Office of Pesticide Programs

Environmental Protection Agency

Room S-4900, One Potomac Yard

2777 South Crystal Drive

Arlington, VA 22202-4501

475423-00

RE: Quillaja Extract (EPA Reg. No. 82572-1)

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

PRIA Category: B730 - Label amendment requiring data submission

Dear Ms. Hollis:

Technology Sciences Group, on behalf of Desert King Chile, is submitting the enclosed amendment to revise the signal word, as well as make other label revisions. Included with this submission, is a product chemistry (amended part A) data volume discussing modifications made to the manufacturing process resulting in Quillaja Extract's decreased eye irritation results.

You will find the following in support of this amendment:

- 1) Amendment application form,
- 2) Certification with respect to data citation,
- 3) Data matrices (confidential and non-confidential versions),
- 4) One redline version of the label,
- 5) Three clean copies of the revised label,
- 6) Transmittal document,
- 7) Data volumes 2-4 (refer to the transmittal document for study title and other information, and
- 8) PRIA pre-payment receipt (Pay.gov Tracking ID: 24UVL1G7; Agency Tracking ID: 74054272520).

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

E-mail tsg@tsgusa.com

<http://www.tsgusa.com>



WASHINGTON

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Please do not hesitate to contact me directly with any questions and/or concerns.

Sincerely,

A handwritten signature in black ink, reading "Heather R. Bjornson", followed by a horizontal line.

Heather R. Bjornson

Regulatory Agent for Desert King Chile/Desert King International

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

VOLUME 1 OF 4 SUBMISSION

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Desert King Chile, Ltd.
Antonio Bellet 77 Of. 401
Providencia, Santiago, Chile

REGULATORY ACTION:

Submission of data to support amending Quillaja Extract; EPA Reg. No. 82572-1.

PRIA Category: B730 – Label amendment requiring data submission.

TRANSMITTAL DATE:

September 15, 2008

LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
	1 of 4	(Transmittal Document)	-----
47542301	2 of 4	Quillaja Extract Product Chemistry –Amended Part A	OPPTS 830.1620
47542302	3 of 4	Quillaja Extract Eye Irritation Study No. BIBR 6 – 9146	OPPTS 870.2400
47542303	4 of 4	Quillaja Extract Eye Irritation Study No. BIBR 6 – 9147	OPPTS 870.2400

COMPANY NAME:

Desert King Chile, Ltd.



COMPANY OFFICIAL:

Heather R. Bjornson, Regulatory Agent

COMPANY CONTACT:

Heather R. Bjornson, Regulatory Agent
Technology Sciences Group, Inc.
1150 18th Street, N.W. Ste. 1000
Washington, DC 20036
(202) 828-8945



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

*File
copy*

October 6, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
OR PAY ON-LINE at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-400157
EPA File Symbol or Registration Number: 82572-1
Product Name: QUILLAJA EXTRACT
EPA Receipt Date: 17-Sep-2008
EPA Company Number: 82572
Company Name: DESERT KING CHILE, LTD.

FXI

HEATHER R. BJORNSON
TECHNOLOGY SCIENCES GROUP, INC.
DESERT KING CHILE, LTD.
1150 18TH ST., NW, SUITE 1000
WASHINGTON, DC 20036-

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action previously identified as B730 has been reclassified as Action Code: B680

AMENDMENT;NON-FAST TRACK;MICROBIAL/BIOCHEMICAL;

The fee associated with this action is \$ 4,200. Payment in the amount of \$ 1,050 has been received. Please remit additional payment in the amount of \$ 3,150 to :

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 11 2007

Heather R. Bjornson
Regulatory Consultant for Desert King Chile, Ltd
Technology Sciences Group, Inc.
1150 18th Street NW, Suite 1000
Washington, DC 20036

Dear Ms. Bjornson:

RE: Desert King Chile Ltd, Quillaja Extract, EPA Reg. No. 82572-R
Pesticide Product Registration Pre-Acceptance Letter

This is a pre-acceptance letter regarding Desert King Chile Ltd's application to register the above referenced product for a Section 3 registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Environmental Protection Agency (EPA) will consider registering Desert King Chile Ltd's product under FIFRA Section 3(c)(7)(A) provided Desert King Chile Ltd Agree to the conditions as defined in this letter.

To enable the Agency to continue to process the subject registration application, EPA requests that Desert King Chile Ltd agree in writing to the following:

1. Desert King Chile Ltd will submit product performance data within one year from the date registration is granted for the product;
2. Desert King Chile Ltd will be required to meet with the appropriate Biochemical Pesticides Branch (BPB) representatives to determine the specific product performance data to be conducted and submitted;
3. Desert King Chile Ltd will be responsible for initiating the meeting referenced above under condition (2) and this meeting shall commence soon after product registration is granted, not to exceed 2 months post registration.

This letter does not constitute a commitment to register the subject product, nor is it intended to imply that EPA will register the subject product. Rather, the purpose of this letter is to inform you that, if Desert King Chile Ltd agrees to the conditions in writing as

described in this letter, EPA will be able to continue to process the registration application in accordance with our normal procedures.

Sincerely,

Linda A. Hollis

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
(7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number:
82572-1

Date of Issuance:

JUL 14 2007

Term of Issuance: **Conditional**

Name of Pesticide Product:

Quillaja Extract

NOTICE OF PESTICIDE:

 X Registration
 Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (Include ZIP Code):

Heather R. Bjornson
Regulatory Consultant for Desert King Chile, Ltd.
Technology Sciences Group, Inc.
1150 18th Street NW, Suite 1000
Washington, DC 20036

808522 / B59
1170

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Sec. 3(c)(7)(A) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit the following data on or before July 30, 2008:
Acceptable efficacy data that supports the claims for the control of nematodes on the representative group of crops and/or turf as to be determined in the meeting between BPPD and Desert King Chile Ltd. two (2) months post registration.
3. Submit three (3) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description and final printed labeling.

Signature of Approving Official:

W. Michael McDavit

Date:

7/14/07

CONCURRENCES

SYMBOL									
SURNAME	Michael McDavit, Associate Director,								
DATE	Biopesticides and Pollution Prevention Division								

This product is conditionally registered under FIFRA Sec. 3(c)(7)(B) because the Agency has imposed the data requirements listed under item 2, above.

The expiration date for this conditionally registered product is July 30, 2008.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Michael McDavit", with a stylized flourish at the end.

W. Michael McDavit
Associate Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures

JUL 12 2007

808522 / B59
1170MEMORANDUM

SUBJECT: Consideration of a conditional registration of the active ingredient Saponins of *Quillaja saponaria* (PC Code 097095, EPA Registration Number 82572-R). This compound will be incorporated into end-use products intended to control plant parasitic nematodes and fungi in vineyards, fields of ornamental plants and food crops.

----- **DECISION MEMORANDUM** -----

FROM: W. Michael McDavit, Associate Director
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs

TO: Debra Edwards, Ph. D., Director
Office of Pesticide Programs

ISSUE

Should the Agency grant a conditional registration under FIFRA § 3(c)(7)(B) for the new biochemical active ingredient, Saponins of *Quillaja saponaria* (PC Code 097095 EPA Registration Number 82572-R) to be used in end-use products intended for agricultural applications for the control of fungi and nematodes in vineyards, field crops and ornamentals?

APPLICANT INFORMATION

On August 26, 2005, the Agency received an application filed by Desert King Chile, Ltd., Antonio Bellet 77 OF.401, Providencia, Santiago, Chile 6640209 (submitted by Technology Sciences Group, Inc., 1101 17th Street, NW, Suite 500, Washington, DC 20026 to register the product Quillaja Extract containing 8.60% of the new biochemical active ingredient, Saponins of *Quillaja saponaria* (PC Code 097095). A notice of receipt of this application was published in the Federal Register April 5, 2006 (71 FR 17095).

CONCURRENCES

SYMBOL	7511P	7511P	7511P					
SURNAME	Bennhard	J. Hany	COLE					
DATE	6/24/07	7/11/07	7/11/07					

BACKGROUND AND CONCLUSIONS

The Biopesticides and Pollution Prevention Division (BPPD) reviewed available and submitted data and information regarding the proposed use of the saponins of *Quillaja saponaria*. Evaluations of the data and conclusions are summarized and discussed in the attached Biopesticide Registration Action Document (BRAD). The technical grade active ingredient (TGAi) is a water extract from the bark of *Quillaja saponaria*. These extracts commonly known as Saponins, are naturally occurring glycosides in tree bark and wood and form soap-like foams in aqueous solution.

BPPD has considered the saponins of *Quillaja saponaria* in light of relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and determined there will be no unreasonable adverse effects from the use of this product. BPPD has considered available data on these Saponins, including the natural occurrence, their common use as food items as emulsifiers in baked goods, candies, frozen dairy products, gelatin, and puddings, and the lack of reported adverse effects. BPPD believes that end use products containing the saponins of *Quillaja saponaria*, can be used without causing unreasonable adverse effects to humans or the environment. BPPD has concluded that this registration should be issued on a conditional basis pending submission of acceptable product performance data.

The data submitted by applicant and reviewed by BPPD support the application to register the product Quillaja Extract containing 8.60% of the new biochemical active ingredient, Saponins of *Quillaja saponaria*, when applied / used as directed on the label and in accordance with good agricultural practices.

OFFICE DIRECTOR CONCURRENCE

Based on the discussion above and the summarized data evaluations in the attached BRAD, BPPD recommends that the product Quillaja Extract containing 8.60% of the new biochemical active ingredient Saponins of *Quillaja saponaria* (PC Code 097095), be conditionally registered under 3(c)(7)(B) of FIFRA for use to control fungi and nematodes in vineyards, field crops and ornamentals.

Concurrence: _____

Robert E. Luman

Non Concurrence: _____

Date: _____

July 15, 2007



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 11 2007

Heather R. Bjornson
Regulatory Consultant for Desert King Chile, Ltd
Technology Sciences Group, Inc.
1150 18th Street NW, Suite 1000
Washington, DC 20036

Dear Ms. Bjornson:

RE: Desert King Chile Ltd, Quillaja Extract, EPA Reg. No. 82572-R
Pesticide Product Registration Pre-Acceptance Letter

This is a pre-acceptance letter regarding Desert King Chile Ltd's application to register the above referenced product for a Section 3 registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Environmental Protection Agency (EPA) will consider registering Desert King Chile Ltd's product under FIFRA Section 3(c)(7)(A) provided Desert King Chile Ltd Agree to the conditions as defined in this letter.

To enable the Agency to continue to process the subject registration application, EPA requests that Desert King Chile Ltd agree in writing to the following:

1. Desert King Chile Ltd will submit product performance data within one year from the date registration is granted for the product;
2. Desert King Chile Ltd will be required to meet with the appropriate Biochemical Pesticides Branch (BPB) representatives to determine the specific product performance data to be conducted and submitted;
3. Desert King Chile Ltd will be responsible for initiating the meeting referenced above under condition (2) and this meeting shall commence soon after product registration is granted, not to exceed 2 months post registration.

This letter does not constitute a commitment to register the subject product, nor is it intended to imply that EPA will register the subject product. Rather, the purpose of this letter is to inform you that, if Desert King Chile Ltd agrees to the conditions in writing as

described in this letter, EPA will be able to continue to process the registration application in accordance with our normal procedures.

Sincerely,

Linda A. Hollis

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

SEP 05 2006

Heather R. Bjornson
Regulatory Consultant for Desert King Chile, Ltd.
Technology Sciences Group, Inc.
1101, 17th Street, N.W., Suite 500
Washington, DC 20036

Subject: Application to Register *Quillaja saponaria* Extract
EPA File Symbol: 82572-R
Application dated: January 25, 2005

Dear Ms. Bjornson:

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the application referred to above, submitted in connection with registration under FIFRA section 3(c)(5). BPPB has concluded your application is **not** acceptable, and that the following deficiencies **must** be addressed before we can proceed with the review of your submission and issue the registration for this product.

BPPD CONCLUSIONS

1. The product chemistry submission for the end-use product (EP) is unacceptable. To upgrade your submission you must:

a. In Column 10 of the CSF: The name of the active ingredient (TGAI) should be stated as "Saponins of *Quillaja saponaria*" containing the following triterpenoid saponins: QS-7, QS 17, QS-18, and QS-21 and their respective percentages in the extract. If chemical names and CAS numbers are available for these four saponins, they must be provided. If available, chemical names (e.g. Quillaic acid 3-O-glucuronide) must be used instead of the QS numbers. The sum of the percentages of all the saponins in the extract will be used to determine the true percentage of active ingredient in the product. You may refer to the BRAD for Saponins of *Chenopodium quinoa* for guidance in describing the active ingredient.

b. Based on the 5-batch analysis of the EP, the percentage by weight of the active ingredient in the product should be 8.6% with upper and lower certified limits of 7.91% and 9.2%, respectively.

CONCURRENCES

SYMBOL	7511P	7511P						
SURNAME	Benmhead	Paul						
DATE	9/1/06	9/1/06						

c. [REDACTED]

d. On the CSF: Instead of listing "Coextractives," separate each of the coextracted components into separate rows of the CSF, as listed in MRID 465684-01 (Table 1., p. 33). Each component must be listed as an inert (other) ingredient with a weight, nominal concentration by percent weight of product, and upper certified limit. Since these coextracted components will be considered manufacturing impurities, no lower certified limit is required.

e. Provide the actual name and address of the source of the ingredient, water.

f. The total weight of product, and some percentages by weight of ingredients are incorrect, but these values may change depending on what ingredient is used to replace [REDACTED].

g. Since there is no discrete TGAI for the product, you must present data/information for color, odor, stability, and boiling point for the product.

2. Toxicity studies

a. Tier I acute oral toxicity, acute dermal toxicity, primary eye irritation, primary dermal irritation, and skin sensitization studies are acceptable. The EP is in Toxicity Category III for acute oral toxicity and acute dermal toxicity; Toxicity Category II for primary eye irritation; and Toxicity Category IV for primary dermal irritation; the product is not a sensitizer. No acute inhalation study was submitted.

b. The waiver request for acute inhalation toxicity is not acceptable. The waiver request is based primarily upon oral toxicity exposure/toxicity data and does not address the inhalation route of exposure. The registrant must either conduct an acute inhalation study using the TGAI, or submit an appropriate waiver request for the data requirements. As an alternative, the Agency would classify the product in acute inhalation toxicity in Toxicity Category II (identical for the Toxicity Category for primary eye irritation) due to its potential to cause irritation to mucosal membranes (including lung tissue).

c. The 90-day feeding study is not acceptable, but upgradeable. To upgrade the study, you must submit for our review and approval the method used to prepare the

diet formulations, and the storage conditions for the test material and the diet formulations.

d. The toxicity information/data submitted in support of waivers for the remainder of the Tier I Toxicity data requirements in conjunction with Agency obtained information, are acceptable; no additional data is required.

3. Non-target organisms

a. Data submitted for avian acute oral toxicity and dietary toxicity are acceptable; no additional data are required for birds. These guideline studies and non-guideline studies found by BPPD scientists in an extensive ECOTOX literature search demonstrate that exposure to *Quillaja saponaria* extract will not adversely affect birds. There are no concerns for non-target birds, including endangered species.

b. Fish acute toxicity data are Acceptable. However, in non-guideline studies identified by BPPD, there are slight indications that long term exposure (8-14 weeks) to high concentrations of Quillaja saponins (150 to 700 ppm) may have teratogenic and/or endocrine effects in fish Nile Tilapia. Since there is insufficient information regarding the potential for run-off following application of the product, you **must** conduct a Fish Life Cycle toxicity study (OPPTS 850.1500) to alleviate concerns regarding potential teratogenic and/or endocrine effects in fresh water fish. Shifts in normal male: female ratios or any other potential teratogenic and/or potential endocrine effects in fish must be reported.

c. A non-guideline aquatic invertebrate acute toxicity study is acceptable, although Daphnids would have been the preferred study organism. The study indicates that Quillaja saponins are slightly toxic to Penaeid shrimp. The same study also indicates that after 36-60 days, exposure to Quillaja saponins, significant reductions in growth, feeding, and molting frequency were observed with a Lowest Observed Effect Concentration (LOEC) of 0.5 ppm and a No Observed Effect Concentration (NOEC) of 0.1 ppm.

d. Based on the observed effects on freshwater fish and an aquatic invertebrate, Tier II Environmental Fate data requirements are **triggered**. Please refer to 40 CFR 158.690(d) "Non-target Organisms, Fate and Expression Data Requirements, Tier II." Alternatively, you may submit requests to waive these data requirements. A waiver request must be submitted for each study, and the request must be based upon a scientifically based rationale, demonstrating that *Quillaja saponaria* extract, when applied according to proposed label directions, will not run-off into aquatic sites in sufficient quantities to induce potential endocrine and/or teratogenic effects and/or will degrade with sufficient rapidity so as not to cause these effects. Please refer to the 40 CFR 158.690 (d) Nontarget organism, fate and expression data requirements - Tier II. Protocols for these test Guidelines may be found in OPPTS Harmonized Guidelines Series 835 Fate, Transport and Transformation Guidelines.

e. There is insufficient information regarding the amount of *Quillaja saponaria* extract that may potentially run-off into aquatic systems via the various label application methods and rates, or as a result of unexpected precipitation events following application, and no information regarding the Estimated Environmental Concentrations (EEC) that may result from this potential run-off. Biotic and abiotic degradation / dissipation rates are also unknown. The proposed repeat applications to soil and foliage, and subsequent run-off, may increase *Quillaja saponaria* extract concentrations in aquatic ecosystems to a level that will result in adverse effects in fish and other aquatic organisms. Therefore, the data obtained from the studies described above will be important for modeling degradation and aquatic EEC for *Quillaja saponins*.

f. A comprehensive Endangered Species Risk Assessment cannot be completed until the deficiencies described in above are resolved.

4. Product performance.

a. The submitted efficacy studies **DO NOT** support proposed label use claims for control or suppression of parasitic nematodes or as a potential plant growth regulator. Studies (MRIDs 466081-15, -16, and -17) supporting proposed label claims for use of the product in controlling powdery mildew on squash are acceptable.

b. The remaining submitted efficacy studies are unacceptable to support efficacy of the proposed EP for the following reasons:

(i) In studies intended to evaluate control of nematodes, nematode data were either not presented or the data did not demonstrate any significant differences.

(ii) One study conducted to evaluate nematode control, presented raw data without any statistical analysis or conclusions by the study authors.

(iii) Some studies were intentionally or unintentionally combined with conventional chemical treatments, which invalidate the studies submitted for the purpose of demonstrating the efficacy of *Quillaja saponaria* extract.

5. The data submitted do not support the registration of the end-use product at this time.

6. Tolerance petition.

The data submitted does not support the petition for an exemption from the requirements of tolerances on all food commodities. Degradation/dissipation rates for the applied active ingredient in the environment are uncertain. Similarly, the potential for human dietary exposure to *Quillaja saponaria* extract from all sources, including exposure to the applied active ingredient, are uncertain.

7. Label deficiencies

BPPD has not completed its review of your product label review at this time pending receipt and acceptance by the Agency of the above data and/or waiver requests. The following label deficiencies have been preliminary identified:

- a. The active ingredient name must be changed to Saponins of *Quillaja saponaria* (comprised primarily of QS-7, QS-17, QS-18, and QS-21). The actual names of the saponins are available, they should be used in place of the QS numbers.
- b. The product label Signal Word must be changed to "Warning," and the Precautionary Statements and First Aid Statements must be revised to accurately reflect the Toxicity Categories for each route of exposure.
- c. The concentration of active ingredient **must be** changed from 7.5% to 8.6%. Data reported in the five-batch analysis indicate that the nominal concentration of Quillaja saponins is 8.6%.
- d. Under Chemigation applications: provide additional information or an explanation regarding the statement: "If a pesticide tank is used, dilute the product with just enough water to assure an application concentration at the end of the irrigation line between 5,000 and 10,000 ppm." This appears to be **an extremely high** application rate that exceeds proposed label application rates. Furthermore, there is no recommended method to measure these concentrations.
- e. The statement "Avoid any runoff of this product in waterways or ponds that would result in contamination of fish" is not sufficient to prevent run-off of product due to human error or an unanticipated precipitation event.
- f. Under Non-Agricultural Uses: Turfgrasses: The statement, "Do not apply within 10 feet of any surface body of water or fairway surface drain," implies that this distance is sufficient to prevent run-off into these sites. At this time, there is insufficient information to verify a sufficient distance to prevent run-off.
- g. Label claims for nematicidal activity and plant growth regulator activity (i.e. increases growth and yield) are not supported by the submitted efficacy studies, and thus these claims must be removed.

Your application as submitted under the Pesticide Registration improvement Act (PRIA) guaranteed you a regulatory decision for the action category B 59 of 15 months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there is not enough time remaining before the PRIA decision date of November 06, 2006 for you to submit the information requested above and for BPPD to complete the review.

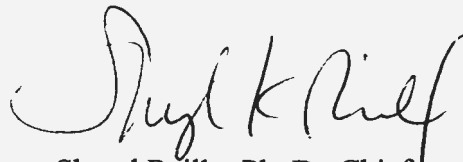
Therefore, you may renegotiate the due date, withdraw the application and resubmit when you have all the information or the Agency will issue "a cannot grant" letter under PRIA.

You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information within 75 days, the Agency will continue to work on your application, but it will not be subject to the PRIA time frame.

Please contact the regulatory action leader, Driss Benmhend, at (703) 308-9525 or at Benmhend.driss@epa.gov, immediately or within 15 days from the date of this letter with your response.

Sincerely,

A handwritten signature in black ink, appearing to read "Sheryl Reilly". The signature is fluid and cursive, with the first name "Sheryl" written in a larger, more prominent script than the last name "Reilly".

Sheryl Reilly, Ph. D., Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

http://epa.gov/EPA-PEST/2006/March/Day-15/
=====

[Federal Register: March 15, 2006 (Volume 71, Number 50)]

[Notices]

[Page 13388-13389]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

[DOCID:fr15mr06-108]

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2006-0193; FRL-7768-2]

Notice of Filing of a Pesticide Petition for the Establishment of
an Exemption from the Requirement of Regulations for Residues of
Quillaja Saponaria in or on All Food Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide
petition proposing the establishment of an exemption from the
requirement of regulations for residues of Quillaja Saponaria extract
in or on all food commodities.

DATES: Comments must be received on or before April 14, 2006.

ADDRESSES: Submit your comments, identified by docket identification
(ID) number EPA-HQ-OPP-2006-0193 and pesticide petition number (PP)
5F6982, by one of the following methods:

? http://www.regulations.gov/.

Follow the on-line

instructions for submitting comments.

? Mail: Public Information and Records Integrity Branch
(PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental
Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

? Hand Delivery: Public Information and Records Integrity
Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP),
Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801
S. Bell St., Arlington, VA, Attention: Docket ID number EPA-HQ-OPP-
2006-0193. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday
through Friday, excluding legal holidays. The telephone number for the
Docket Facility is (703) 305-5805. Such deliveries are only accepted
during the Docket's normal hours of operation, and special arrangements
should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-
2006-0193. EPA's policy is that all comments received will be included
in the public docket without change and may be made available on-line
at http://www.regulations.gov/,
including any personal
information provided, unless the comment includes information claimed to
be Confidential Business Information (CBI) or other information whose
disclosure is restricted by statute. Do not submit information that you
consider to be CBI or otherwise protected through regulations.gov or e-
mail. The http://www.regulations.gov
website is an "anonymous
access" system, which means EPA will not know your identity or contact

Brian
Steinwand/DC/USEPA/US
03/15/2006 12:53 PM

To OPP BPPD
cc
bcc
Subject Fw: [epa-pest] Notice of Filing of a Pesticide Petition for the
Establishment

information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going at [regulations.gov](http://www.regulations.gov), your e-mail address will be captured automatically and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the [regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at <http://www.regulations.gov> or in hard copy at the Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Driss Benmhend, Biopesticides and Pollution Prevention Division, (7511C), Office of Pesticide Programs, U. S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; (703) 308-9525; e-mail: <mailto:benmhend.driss@epa.gov>; benmhend.driss@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- ? Crop production (NAICS code 111).
- ? Animal production (NAICS code 112).
- ? Food manufacturing (NAICS code 311).
- ? Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed at the end of the pesticide petition summary of interest.

B. What Should I Consider as I Prepare My Comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the

information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, Federal Register date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

[[Page 13389]]

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. What Action is the Agency Taking?

EPA is printing a summary of each pesticide petition received under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, proposing the establishment or amendment of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. EPA has determined that this pesticide petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petition. Additional data may be needed before EPA rules on this pesticide petition.

Pursuant to 40 CFR 180.7(f), a summary of the petition included in this notice, prepared by the petitioner along with a description of the analytical method available for the detection and measurement of the pesticide chemical residues is available on EPA's Electronic Docket at <http://www.regulations.gov/>. To locate this information on the home page of EPA's Electronic Docket, select ``Quick Search'' and type the OPP docket ID number. Once the search has located the docket, clicking on the ``Docket ID'' will bring up a list of all documents in the docket for the pesticide including the petition summary.

New Exemption from Tolerance

PP 5F-982. Desert King Chile, Ltd., Antonio Bellet 77 OF.401, Providencia, Santiago, Chile 6640209 (submitted by Technology Sciences Group, Inc., 1101 17th Street, NW, Suite 500, Washington, DC 20026),

proposes to establish an exemption from the requirement of a tolerance for residues of the biopesticide Quillaja Saponaria, extract in or on all food commodities. Because this petition is a request for an exemption from the requirement of a tolerance without numerical limitations, no analytical method is required.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 7, 2006.

Janet L. Andersen,
Director, Biopesticides and Pollution Prevention Division, Office of
Pesticide Programs.

[FR Doc. E6-3738 Filed 3-14-06; 8:45 am]

BILLING CODE 6560-50-S

<http://www.epa.gov/fedrgstr/EPA-PEST/index.html>
Comments: <http://www.epa.gov/fedrgstr/comments.htm>
Search: <http://epa.gov/fedreg/search.htm>
EPA's Federal Register: <http://epa.gov/fedreg/>

2 February 2006

Heather R. Bjornson
Regulatory Consultant for Desert King Chile, Ltd.
Technology Sciences Group, Inc.
1101 17th Street, NW
Suite 500
Washington, DC 20036

RE: Product Name: Quillaja Extract
EPA Reg.#/File Symbol: 82572-R
Application dated: January 25, 2005 (erroneously dated)
Notification of Non-compliance with Pesticide Registration Notice 86-5

Fax sent date: 2-2-06
Fax number: 202-223-4392

Dear Ms. Bjornson:

The Biopesticides and Pollution Prevention Division (BPPD) has received your submission to register the subject product. All or some of the data were rejected our Document Processing Unit because they were not submitted as directed in PR Notice 86-5 and should be reformatted and resubmitted to the Document Processing Unit. A copy of PR Notice 86-5 can be found at our website at: http://www.epa.gov/opppmsd1/PR_Notices/pr86-5.html should you need assistance in making the necessary changes.

If you still want to register this product, the application will be kept open for a period of 75 days to give you an opportunity to respond to this memorandum. If you find that you need more time you must request an extension for a reasonable stated period of time. Extension requests must be made immediately to) at (703) 308-8733.

If you do not comply with this procedure by not responding to this letter or requesting an extension of time to resubmit the information, the Agency may administratively withdraw your application from further consideration. Under the provisions of PR Notice 75-4 of August 27, her. Once this is done, you will have to submit completely new application should you wish to pursue the registration of your product after the application has been withdrawn.

The changes and/or corrections required by you are outlined in the attached EPA Transmittal Letter. You must contact Linda Hollis and indicate and that you will submit the corrected pages via facsimile to: (703) 308-8733. If the changes are excessive, you may wish to

fed-ex or courier the documents to our offices or contact Linda Hollis to arrange to come in to our offices to make the necessary changes. Once all changes have been made, your submission will be forwarded to our Document Processing Unit for PR Notice 86-5 Screening.

Should you have additional questions regarding this matter, the Team Leader for this Biochemical Pesticide Product is Linda Hollis @ hollis.linda@epa.gov.

Sincerely,

Linda Hollis

Linda Hollis, Team Leader
Biopesticides and Pollution Prevention Division
Biochemical Pesticides Branch

Attachment

**WASHINGTON**

1101 17th Street, N.W.
Suite 500
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Sheryl Reilly
Chief, Biochemical Pesticide Branch
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs, EPA
1801 South Bell Street, CM2
Arlington, VA 22202

January 25, 2005

RE: Desert King Chile: Quillaja Extract (EPA File No. 82572-R)**Submission of acute inhalation and skin sensitization studies****SACRAMENTO**

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

Dear Dr. Reilly:

Technology Sciences Group Inc., on behalf of Desert King Chile, Ltd, is submitting the enclosed acute toxicity studies to support the application for registration of the above referenced product. The acute inhalation data requirement was addressed in the original application for registration with a waiver request. The skin sensitization study has been re-performed to meet US guidelines.

You will find the following in support of this submission:

- 1) Application form,
- 2) Transmittal Document (Volume 1),
- 3) Acute Inhalation Toxicity of Quillaja Extract (Volume 2 – 3 copies), and
- 4) Skin Sensitization of Quillaja Extract (Volume 3 – 3 copies).

CANADA

275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

Please do not hesitate to contact me directly at (202) 828-8945 or via e-mail hbjornson@tsqusa.com with any questions and/or concerns.

Sincerely,

Heather R. Bjornson
Regulatory Consultant for Desert King Chile, Ltd.

cc: Rodrigo Otero, Desert King International
Paulo Tamargo, Desert King Chile, Ltd.

VOLUME 1 OF 3 SUBMISSION

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Desert King Chile, Ltd.
Antonio Bellet 77 Of. 401
Providencia, Santiago, Chile

REGULATORY ACTION:

Submission of acute toxicity studies to support the application for registration of Quillaja Extract (EPA File No. 82572-R).

TRANSMITTAL DATE:


January 25, 2006

LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
	1 of 3	(Transmittal Document)	-----
46774901	2 of 3	Quillaja Extract Acute Inhalation Toxicity	870.1300
46741302	3 of 3	Quillaja Extract Skin Sensitization	870.2600

COMPANY NAME: Desert King Chile, Ltd.

COMPANY OFFICIAL:


Heather R. Bjornson, Regulatory Agent

COMPANY CONTACT:

Heather R. Bjornson, Regulatory Agent
Technology Sciences Group, Inc.
1101 17th Street, N.W. Ste. 500
Washington, DC 20036
(202) 828-8945

[Federal Register: April 5, 2006 (Volume 71, Number 65)]
[Notices]
[Page 17095-17096]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr05ap06-62]

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2006-0189-FRL-7769-3]

Pesticide Product; Registration Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register pesticide products containing a new active ingredient, Quillaja Saponaria Extract, not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Comments must be received on or before May 5, 2006.

ADDRESS: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2006-0189, by one of the following methods:

<http://www.regulations.gov/>. Follow the on-line

instructions for submitting comments.

Mail. Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

Hand delivery. Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall 2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number EPA-HQ-OPP-2006-0189. The docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the docket facility is (703) 305-5805. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions. Direct your comments to docket ID number EPA-HQ-OPP-2006-0189. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at <http://www.regulations.gov/>, including any personal information

provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov/) or e-mail. The [regulations.gov](http://www.regulations.gov/) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov/), your e-mail address will be captured automatically and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic

files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/docket.htm/>.

Docket. All documents in the docket are listed in the regulation.gov index. Although, listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at <http://www.regulations.gov/> or in hard copy at the Public

Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall 2, 1801 S. Bell St., Arlington, VA. The docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the docket facility is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Driss Benmhend, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9525; e-mail address: benmhend.driss@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of

[[Page 17096]]

this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. What Should I Consider as I Prepare My Comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through <http://www.regulations.gov> or e-mail. Clearly mark the part or all of the

information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI). In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When submitting comments,

remember to:

- i. Identify the document by docket number and other identifying information (subject heading, Federal Register date and page number).
- ii. Follow directions. The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns, and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Registration Applications

EPA received applications as follows to register pesticide products containing active ingredients not included in any previously registered products pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

File Symbol: 82572[dash]R. Applicant: Desert King Chile, Ltd. Antonio Bellet 77 OF.401, Providencia, Santiago, Chile 6640209. Product name: Quillaja Saponaria Extract. Type of product: biochemical nematocide, Manufacturing Use product. Active Ingredient: Quillaja Saponaria Extract at 7.50%. Proposed classification/Use: For formulation into end-use products for control of nematodes.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: March 21, 2006.

Janet L. Andersen,
Director, Biopesticides and Pollution Prevention Division, Office of
Pesticide Programs.
[FR Doc. E6-4763 Filed 4-4-06; 8:45 am]

BILLING CODE 6560-50-S

http://epa.gov/EPA-PEST/2006/April/Day-05/
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[Federal Register: April 5, 2006 (Volume 71, Number 65)]
[Notices]
[Page 17095-17096]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr05ap06-62]

ENVIRONMENTAL PROTECTION AGENCY
[EPA-HQ-OPP-2006-0189-FRL-7769-3]

Pesticide Product; Registration Applications

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register pesticide products containing a new active ingredient, Quillaja Saponaria Extract, not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Comments must be received on or before May 5, 2006.

ADDRESS: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2006-0189, by one of the following methods:

<?http://www.regulations.gov/.

Follow the on-line

instructions for submitting comments.

<?Mail. Public Information and Records Integrity Branch
(PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental
Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-
0001.

Hand delivery. Public Information and Records Integrity Branch
(PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental
Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St.,
Arlington, VA, Attention: Docket ID number EPA-HQ-OPP-2006-0189. The
docket facility is open from 8:30 a.m. to 4 p.m., Monday through
Friday, excluding legal holidays. The telephone number for the docket
facility is (703) 305-5805. Such deliveries are only accepted during
the Docket's normal hours of operation, and special arrangements should
be made for deliveries of boxed information.

Instructions. Direct your comments to docket ID number EPA-HQ-OPP-
2006-0189. EPA's policy is that all comments received will be included
in the public docket without change and may be made available on-line
at http://www.regulations.gov/,
including any personal information
provided, unless the comment includes information claimed to be
Confidential Business Information (CBI) or other information whose
disclosure is restricted by statute. Do not submit information that you
consider to be CBI or otherwise protected through regulations.gov or e-
mail. The regulations.gov website is an ``anonymous access'' system,
which means EPA will not know your identity or contact information

Brian
Steinwand/DC/USEPA/US
04/05/2006 02:06 PM

To OPP BPPD
cc
bcc
Subject Fw: [epa-pest] Pesticide Product; Registration Applications

unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be captured automatically and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/docket.htm>.

Docket. All documents in the docket are listed in the regulation.gov index. Although, listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at <http://www.regulations.gov/> or in hard copy at the Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. The docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the docket facility is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Driss Benmhend, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9525; e-mail address: <mailto:benmhend.driss@epa.gov>.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- <?Crop production (NAICS code 111).
- <?Animal production (NAICS code 112).
- <?Food manufacturing (NAICS code 311).
- <?Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of

[[Page 17096]]

this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. What Should I Consider as I Prepare My Comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through http://www.regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI). In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When submitting comments, remember to:

- i. Identify the document by docket number and other identifying information (subject heading, Federal Register date and page number).
- ii. Follow directions. The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns, and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Registration Applications

EPA received applications as follows to register pesticide products containing active ingredients not included in any previously registered products pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

File Symbol: 82572[dash]R. Applicant: Desert King Chile, Ltd. Antonio Bellet 77 OF.401, Providencia, Santiago, Chile 6640209. Product name: Quillaja Saponaria Extract. Type of product: biochemical nematocide, Manufacturing Use product. Active Ingredient: Quillaja Saponaria Extract at 7.50%. Proposed classification/Use: For formulation into end-use products for control of nematodes.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: March 21, 2006.

Janet L. Andersen,
Director, Biopesticides and Pollution Prevention Division, Office of
Pesticide Programs.

[FR Doc. E6-4763 Filed 4-4-06; 8:45 am]

BILLING CODE 6560-50-S



U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES (OPPTS)
1200 Pennsylvania Avenue, N.W. , Washington, D.C. 20460

DOCKET VERIFICATION AND CERTIFICATION FORM
For Internal OPPTS Use Only

Title of Action: Notice of Filing of a Pesticide Petition for the Establishment of an Exemption from the Requirement of a Tolerance for Residues of the Biopesticide Quillaja Saponaria in or on All Food Commodities

RIN #: 2070-

Docket ID #: EPA-HQ-OPP-2006-0193

FRL#:

Docket Title: EPA-HQ-OPP-2006-0193 Containing PP# 5F6982 (Quillaja Saponaria in or on All Food Commodities)

Contact Information:

Name:

DRISS BENMHEM

Phone:

703-308-9525

Legacy Information:

Program Lead's Verification: I have reviewed the docket and verified the following:

- ☒ All of the documents identified in the attached Docket Index have been submitted to the appropriate Docket Manager for inclusion in the docket identified above.
- ☒ Documents containing copyrighted, CBI or otherwise protected information have been identified to allow for "special" processing by the docket.
- ☒ The material has been assembled in a useable form to support the document being published in the FEDERAL REGISTER.
- ☒ Comments: Terri Stowe of RD/RSB (703-305-6117) prepared the FR NOF and opened this docket. However, Leonard Cole is the primary Contact Person. Estimated FR publish date: 03/15/06.

Date: 03/ /06

Initials:

DB

Phone:

703-308-9525

Docket Manager's Verification and Sign-off: I hereby confirm the following:

- ☐ The Docket ID # identified above matches our records.
- ☐ The documents identified in the attached Docket Index have been received by the Docket.
- ☐ The documents have been properly processed for inclusion in EPA Dockets, as appropriate.
- ☐ The documents either already are in the docket or are being process for inclusion in the docket.
- ☐ Comments:

Date:

Signature:

[Signature]

Phone:

Program Lead's Certification: I hereby certify that:

- ☒ I have completed the verification above.
- ☒ I have submitted to the DM all of the documents that I identified needed to be updated, or added to the docket.
- ☒ I have obtained the DM's sign-off.
- ☒ The docket is complete and ready for public release.
- ☐ Comments:

Date: 03/ /06

Signature:

Phone: 703-

Attachment: List of Documents For Docket ID # EPA-HQ-OPP-2006-0193 (as of 03/01/06)

| Document Title | Source Information: author (last, first); org.; citation | Date of Document | 1) CBI 2) Other protected, e.g., study 3) Copyrighted |
|--|---|------------------|---|
| 1. Desert King Chile, Ltd.'s (Technology Sciences Group, Inc.) Federal Register Notice of Filing | Desert King Chile, Ltd.'s (Technology Sciences Group, Inc.) | ?? | N/A - No screens required. |
| 2. Federal Register Vol. ??, No. ?? Notices [PF-???; FRL-???-?], ?? FR ???? | Cole, Leonard; EPA/ OPP/BPPD; 703-305-5412 | March ??, 2006 | N/A - No screens required. |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 19, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DESERT KING CHILE, LTD.
1150 18TH ST., NW, SUITE 1000
WASHINGTON, DC 20036-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 17-SEP-08. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

| Receipt for Section 3 | | | |
|---|---|---|-----------------|
| S: 836283 | Fast Track/Exemption: Yes <input type="radio"/> No <input checked="" type="radio"/> | <div>Print Letter</div> <div>Enter More Information</div> <div>Tracking</div> | |
| Regulatory Type: Product Registration - Section 3 | Service: Yes <input type="radio"/> No <input checked="" type="radio"/> | | |
| Application Type: Amendment | Billable: Yes <input checked="" type="radio"/> No <input type="radio"/> | | |
| Company: 82572 DESERT KING CHILE, LTD. | | | |
| Risk Manager: Biologicals & Pollution Prevention Division, PM Team 94 | | | |
| Product #: 82572-1 | Product Name: QULLAJA-EXTRACT | | |
| Event Date: | | | |
| Me Too Section 3: | Me Too Product Name: | | |
| Application Date: 15-Sep-2008 | OPP Rec'd Date: 17-Sep-2008 | <div>Receipt Content</div> <div>Study</div> | |
| Front End Date: 17-Sep-2008 | Risk Manager Send Date: | | |
| FFS Due Date: | Negotiated Due Date: | | |
| OPP Target Date: | | | |
| Fast Track: <input type="checkbox"/> | New Ingredient: <input type="checkbox"/> | | |
| Receipt Description: Label amendment requiring data submission | | <div>New Ingredient Received Date:</div> <div>New Ingredient Received Date:</div> | |
| Form A: <input type="checkbox"/> | Signature Date: | Form B: <input type="checkbox"/> | Signature Date: |

B680 - Non Fast Team (Driss)

To John F.
OCT 08 2008
Pm

Please transfer Jacket to
your name.
Thanks.

LH
10/4/08

AIO-Driss
OCT 7 2008
sdh



WASHINGTON

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Linda Hollis

September 15, 2008

Chief, Biopesticide and Pollution Prevention Division

Office of Pesticide Programs

Environmental Protection Agency

Room S-4900, One Potomac Yard

2777 South Crystal Drive

Arlington, VA 22202-4501

475423-00

RE: Quillaja Extract (EPA Reg. No. 82572-1)

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

PRIA Category: B730 - Label amendment requiring data submission

Dear Ms. Hollis:

Technology Sciences Group, on behalf of Desert King Chile, is submitting the enclosed amendment to revise the signal word, as well as make other label revisions. Included with this submission, is a product chemistry (amended part A) data volume discussing modifications made to the manufacturing process resulting in Quillaja Extract's decreased eye irritation results.

You will find the following in support of this amendment:

- 1) Amendment application form,
- 2) Certification with respect to data citation,
- 3) Data matrices (confidential and non-confidential versions),
- 4) One redline version of the label,
- 5) Three clean copies of the revised label,
- 6) Transmittal document,
- 7) Data volumes 2-4 (refer to the transmittal document for study title and other information, and
- 8) PRIA pre-payment receipt (Pay.gov Tracking ID: 24UVL1G7; Agency Tracking ID: 74054272520).

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

E-mail tsg@tsgusa.com

<http://www.tsgusa.com>



WASHINGTON

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Please do not hesitate to contact me directly with any questions and/or concerns.

Sincerely,

A handwritten signature in black ink that reads "Heather R. Bjornson" followed by a horizontal line.

Heather R. Bjornson

Regulatory Agent for Desert King Chile/Desert King International

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

E-mail tsg@tsgusa.com

<http://www.tsgusa.com>

VOLUME 1 OF 4 SUBMISSION

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Desert King Chile, Ltd.
Antonio Bellet 77 Of. 401
Providencia, Santiago, Chile

REGULATORY ACTION:

Submission of data to support amending Quillaja Extract; EPA Reg. No. 82572-1.

PRIA Category: B730 – Label amendment requiring data submission.

TRANSMITTAL DATE:

September 15, 2008

LIST OF SUBMITTED STUDIES:

| MRID
NUMBER | VOLUME
NUMBER | EPA STUDY TITLE | GUIDELINE
NUMBER |
|----------------|------------------|---|---------------------|
| | 1 of 4 | (Transmittal Document) | ----- |
| 47542301 | 2 of 4 | Quillaja Extract
Product Chemistry –Amended Part A | OPPTS 830.1620 |
| 47542302 | 3 of 4 | Quillaja Extract
Eye Irritation Study
No. BIBR 6 – 9146 | OPPTS 870.2400 |
| 47542303 | 4 of 4 | Quillaja Extract
Eye Irritation Study
No. BIBR 6 – 9147 | OPPTS 870.2400 |

COMPANY NAME: Desert King Chile, Ltd.



COMPANY OFFICIAL:

Heather R. Bjornson, Regulatory Agent

COMPANY CONTACT:

Heather R. Bjornson, Regulatory Agent
Technology Sciences Group, Inc.
1150 18th Street, N.W. Ste. 1000
Washington, DC 20036
(202) 828-8945



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 18, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-400157
EPA File Symbol or Registration Number: 82572-1
Product Name: QUILLAJA EXTRACT
EPA Receipt Date: 17-Sep-2008
EPA Company Number: 82572
Company Name: DESERT KING CHILE, LTD.

HEATHER R. BJORNSON
TECHNOLOGY SCIENCES GROUP, INC.
DESERT KING CHILE, LTD.
1150 18TH ST., NW, SUITE 1000
WASHINGTON, DC 20036-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B730

AMENDMENT;SCLP;NON-FAST-TRACK 1;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,

A handwritten signature in cursive script that reads "Teresa Downs".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

^{pen 15}
{836293;~

This package includes the following

☐ New Registration

☒ Amendment

☒ Studies? ☐ Fee Waiver?

[✓]
volpay % Reduction: ____

for Division

☐ AD

☒ BPPD

☐ RD

Risk Mgr.

91

Receipt No.

S-

836293

EPA File Symbol/Reg. No.

82572-1

Pin-Punch Date:

9/17/2008

☐

This item is NOT subject to FFS action.

Action Code:

Requested:

B730

Granted:

B730

Amount Due: \$ 1,050

Parent/Child Decisions:

☒ Inert Cleared for Intended Use



☐ Uncleared Inert in Product

Reviewer: L. Cole

Date: 9/17/08

Remarks:

Receipt for Section 3

S: 836283

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 82572 DESERT KING CHILE, LTD.

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 82572-1

Product Name: QUILLAJA EXTRACT

Override:

Me Too

Me Too

Section3:

Product Name:

Application Date: 15-Sep-2008

iel

OPP Rec'd Date: 17-Sep-2008

iel

Front End Date: 17-Sep-2008

iel

Risk Manager Send Date:

iel

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Study

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Label amendment requiring data submission

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

| EPA Receipt Date: SEP 17 2008 | | EPA Reg. Number: 82572-1 | | |
|--------------------------------------|---|---------------------------------|----|-----|
| | Check List Item | Yes | No | N/A |
| 1 | Has the PRIA Fee been Paid ; is a copy of the check or Pay.gov receipt included in the Submission Package? | X | | |
| 2 | Is an Application Form (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type? | X | | |
| 3 | Is a Confidential Statement of Formula (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)? | | X | |
| 4 | Is a Formulator's Exemption Statement (EPA Form 8570-27) Included in the Submission Package? | | X | |
| 5 | Is a Certification with Respect to Citation of Data (EPA Form 8570-34) Included in the Submission Package? | X | | |
| 6 | Is a Data Matrix (EPA Form 8570-35) Included in the Submission Package? | X | | |
| 7 | Is a Label Included in the Submission Package? | X | | |
| 8 | Are Data Included in the Submission Package? | X | | |
| 9 | Is the Submission an Amendment? | X | | |

Heather Bjornson

From: paygovadmin@mail.doc.twai.gov
Sent: Monday, September 15, 2008 4:46 PM
To: Heather Bjornson
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

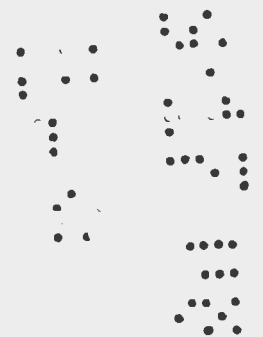
Your transaction has been successfully completed.

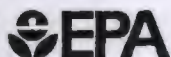
Payment Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 24UVL1G7
Agency Tracking ID: 74054272520

Account Holder Name: Megha S Even
Transaction Type: Sale
Billing Address: 1150 18th St NW
Billing Address 2: Suite 1000
City: Washington
State/Province: DC
Zip/Postal Code: 20036
Country: USA
Card Type: American Express
Card Number: *****1469
Expiration Date: Apr, 2011
Payment Amount: \$1,050.00
Transaction Date: Sep 15, 2008 4:45:34 PM

Decision Number:
Registration Number: 82572-1





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|--|--|--|
| 1. Company/Product Number
82572-1 | 2. EPA Product Manager
Linda Hollis | 3. Proposed Classification
<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name)
Quillaja Extract | PM#
BPPD/Biochemical Pesticides | |
| 5. Name and Address of Applicant (Include ZIP Code)
Desert King Chile, Ltd.
Antoinio Bellet 77 Of 401
Providencia, Santiago, Chile
<input type="checkbox"/> Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____ | |

Section - II

| | |
|--|--|
| <input checked="" type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

PRIA Category B730 - Label amendment requiring data submission.

PRIA pre-payment: Pay.gov Tracking ID: 24UVL1G7; Agency Tracking ID: 74054272520

Section - III

| | | | | | |
|--|--|---|---|--|-------------------|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging
<input type="checkbox"/> Yes
<input checked="" type="checkbox"/> No | Unit Packaging
<input type="checkbox"/> Yes
<input checked="" type="checkbox"/> No | Water Soluble Packaging
<input type="checkbox"/> Yes
<input checked="" type="checkbox"/> No | <input type="checkbox"/> Metal
<input checked="" type="checkbox"/> Plastic
<input type="checkbox"/> Glass
<input type="checkbox"/> Paper
<input type="checkbox"/> Other (Specify) _____ | | |
| * Certification must be submitted | | If "Yes" Unit Packaging wgt. | No. per container | If "Yes" Package wgt | No. per container |
| 3. Location of Net Contents Information
<input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container
5 gal pail; 30 & 55 g drum; 270g tote | | 5. Location of Label Directions
<input checked="" type="checkbox"/> | |
| 6. Manner in Which Label is Affixed to Product
<input checked="" type="checkbox"/> Lithograph
<input checked="" type="checkbox"/> Paper glued
<input checked="" type="checkbox"/> Stenciled | | | <input type="checkbox"/> Other _____ | | |

Section - IV

| | | | |
|---|--|--|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | |
| Name
Heather R. Bjornson, Technology Sciences Group, Inc. | | Title
Regulatory Consultant | |
| | | Telephone No. (Include Area Code)
(202) 828-8945 | |
| Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.
I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | 6. Date Application Received
(Stamped)
 |
| 2. Signature
 | | 3. Title
Regulatory Consultant to Desert King Chile | |
| 4. Typed Name
Heather R. Bjornson | | 5. Date
September 15, 2008 | |
| | | | |



WASHINGTON

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Linda Hollis

September 15, 2008

Chief, Biopesticide and Pollution Prevention Division

Office of Pesticide Programs

Environmental Protection Agency

Room S-4900, One Potomac Yard

2777 South Crystal Drive

Arlington, VA 22202-4501

RE: Quillaja Extract (EPA Reg. No. 82572-1)

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

PRIA Category: B730 - Label amendment requiring data submission

Dear Ms. Hollis:

Technology Sciences Group, on behalf of Desert King Chile, is submitting the enclosed amendment to revise the signal word, as well as make other label revisions. Included with this submission, is a product chemistry (amended part A) data volume discussing modifications made to the manufacturing process resulting in Quillaja Extract's decreased eye irritation results.

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- 1) Amendment application form,
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- 7) Data volumes 2-4 (refer to the transmittal document for study title and other information, and
- 8) PRIA pre-payment receipt (Pay.gov Tracking ID: 24UVL1G7; Agency Tracking ID: 74054272520).

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754



WASHINGTON

1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Please do not hesitate to contact me directly with any questions and/or concerns.

Sincerely,

Heather R. Bjornson
Regulatory Agent for Desert King Chile/Desert King International

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

CANADA

275 Slater Street
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<http://www.tsgusa.com>

VOLUME 1 OF 4 SUBMISSION

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Desert King Chile, Ltd.
Antonio Bellet 77 Of. 401
Providencia, Santiago, Chile

REGULATORY ACTION:

Submission of data to support amending Quillaja Extract; EPA Reg. No. 82572-1.

PRIA Category: B730 – Label amendment requiring data submission.

TRANSMITTAL DATE:

September 15, 2008

LIST OF SUBMITTED STUDIES:

| MRID
NUMBER | VOLUME
NUMBER | EPA STUDY TITLE | GUIDELINE
NUMBER |
|----------------|------------------|---|---------------------|
| | 1 of 4 | (Transmittal Document) | ----- |
| | 2 of 4 | Quillaja Extract
Product Chemistry –Amended Part A | OPPTS 830.1620 |
| | 3 of 4 | Quillaja Extract
Eye Irritation Study
No. BIBR 6 – 9146 | OPPTS 870.2400 |
| | 4 of 4 | Quillaja Extract
Eye Irritation Study
No. BIBR 6 – 9147 | OPPTS 870.2400 |

COMPANY NAME:

Desert King Chile, Ltd.

Heather R. Bjornson

COMPANY OFFICIAL:

Heather R. Bjornson, Regulatory Agent

COMPANY CONTACT:

Heather R. Bjornson, Regulatory Agent
Technology Sciences Group, Inc.
1150 18th Street, N.W. Ste. 1000
Washington, DC 20036
(202) 828-8945



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401 M Street, S.W.
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Certification with Respect to Citation of Data

| | |
|---|--|
| Applicant's/Registrant's Name, Address, and Telephone Number
Desert King Chile, Ltd. Antonio Bellet 77 Of. 401, Providencia, Santiago, Chile Tel. 800 982 2235 | EPA Registration Number/File Symbol
82572-1 |
| Active Ingredient(s) and/or representative test compound(s)
Quillaja saponins | Date
September 15, 2008 |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
Terrestrial: Food crop, Nonfood | Product Name
Quillaja Extract |

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

| | |
|--|---|
| <input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). | <input checked="" type="checkbox"/> I am using the selective method of support (or the cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used). |
|--|---|

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| | | |
|---|-------------------|--|
| Signature
<i>Heather R. Bjornson</i> | Date
9/15/2008 | Typed or Printed Name and Title
Heather R. Bjornson, Regulatory Agent |
|---|-------------------|--|



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DATA MATRIX

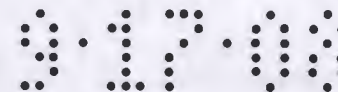
| Date September 15, 2008 | | EPA Reg. No./File Symbol
82572-1 | | Page 1 of 6 | |
|---|---|---|---|-------------|----------------------------|
| Applicant's/Registrant Name and Address
Desert King Chile
Antonio Bellet 77 Of. 401
Providencia, Santiago, Chile | | Product

Quillaja Extract | | | |
| Ingredient Quillaja saponins | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| OPPTS 830.1550 | Product Identity and Composition | 46568401
46972501 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.1600 | Description of Materials Used to Manufacture Product | 46568401
46972501 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.1600 | Description of Production Process | 46568401
46972501 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.1620 | Description of the Formulation Process | 46568401
46972501
This submission | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.1670 | Discussion of the Formation of Impurities | 46568401
46972501 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.1750 | Certified Limits | 46568401
46972501 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.1800 | Enforcement Analytical Method | 46568401
46972501 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.6302 | Color | 46568402
46972502 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.6303 | Physical State | 46568402 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.6304 | Odor | 46568402
46972504 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.6313 | Stability to normal and elevated temperatures, metals and metal ions-TGAI | 46568402
46972502 | Desert King Chile | OWN | 6/7/2005 submission |
| Signature
<i>Heather R. Bjornson</i> | | | Name and Title
Heather R. Bjornson, Regulatory Agent | | Date
September 15, 2008 |



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| Date September 15, 2008 | | | EPA Reg. No./File Symbol
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|--|---|----------------------|---|--------|----------------------------|
| Applicant's/Registrant Name and Address

Desert King Chile
Antonio Bellet 77 Of . 401
Providencia, Santiago, Chile | | | Product

Quillaja Extract | | |
| Ingredient Quillaja saponins | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| OPPTS 830.7000 | pH | 46568402 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.7100 | Viscosity | 46568402 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.7200 | Melting Point/ melting range - PAI | 46568402 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.7220 | Boiling Point/boiling range - PAI | 46568402
46972502 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.7300 | Density, Bulk Density, Specific Gravity | 46568402 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.6314 | Oxidation/Reduction | 46568402 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.6315 | Flammability | 46568402 | Desert King Chile | OWN | 6/7/2005 submission |
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| | | | | | |
| | | | | | |
| Signature <i>Heather R Bjornson</i> | | | Name and Title
Heather R. Bjornson, Regulatory Agent | | Date
September 15, 2008 |



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Date September 15, 2008

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Applicant's/Registrant Name and Address

Desert King Chile
Antonio Bellet 77 Of. 401
Providencia, Santiago, Chile

Product

Quillaja Extract

Ingredient Quillaja saponins

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|---|-------------|-------------------|--------|---------------------|
| OPPTS 830.6317 | Storage Stability | 46568402 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.6319 | Miscibility | 46568402 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.6320 | Corrosion Characteristics | 46568402 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.7750 | Partition coefficient | 46568402 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.7840, 830. 7860 | Water solubility | 46568402 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.7950 | Vapor Pressure | 46568402 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 830.7050 | UV Absorption | 46972503 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 830.7560 | Partition Coefficient, Kow | 46972503 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 830.7950 | Volatility | 46972503 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 835.1210 | Soil thin layer chromatography | | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 835.1220 | Sediment and soil adsorption / desorption | 46972503 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 835.2110 | Hydrolysis as a function of pH | 46972503 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 835.2210 | Direct photolysis rate in water by sunlight | 46972503 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 835.3100 | Aerobic aquatic biodegradation | 46972503 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 835.3300 | Soil biodegradation | 46972503 | Desert King Chile | OWN | WAIVER REQUEST |

Name and Title
Heather R. Bjornson, Regulatory AgentDate
September 15, 2008



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|--|-------------------------------------|-------------|
| Date September 15, 2008 | EPA Reg. No./File Symbol
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| Applicant's/Registrant Name and Address
Desert King Chile
Antonio Bellet 77 Of . 401
Providencia, Santiago, Chile | Product
Quillaja Extract | |

Ingredient Quillaja saponins

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|--|-----------------------------|-------------------|--------|---------------------|
| OPPTS 850.1400 | Fish Life Cycle Toxicity | 46972503 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 870.1100 | Acute Oral Toxicity | 46608101 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 870.1200 | Acute Dermal Toxicity | 46608102 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 870.1300 | Acute Inhalation Toxicity | 46774901 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 870.2400 | Primary Eye Irritation | 46608103
This submission | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 870.2500 | Primary Dermal Irritation | 46608104 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 870.2600 | Dermal Sensitization | 46608105
46741302 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 870.3100 | Subchronic Dietary Toxicity | 46608106 | Desert King Chile | PL | 6/7/2005 submission |
| OPPTS 870.3250 | 90-Day Dermal Toxicity | 46608110 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 870.3465 | 90-Day Inhalation Toxicity | 46608110 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 870.3700 | Teratogenicity | 46608110 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 870.4100 | Chronic Dietary Toxicity | 46608107 | Desert King Chile | PL | 6/7/2005 submission |
| OPPTS 870.4300 | Chronic Toxicity/Carcinogenicity | 46608108 | Desert King Chile | PL | 6/7/2005 submission |
| OPPTS 870.5000 | Genotoxicity | 46608110 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 850.1010 | Aquatic Invertebrate Toxicity | 46608110 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 850.1075 | Acute Toxicity of Freshwater Fish (Carp) | 46608109 | Desert King Chile | OWN | 6/7/2005 submission |

Signature

Name and Title

Heather R. Bjornson, Regulatory Agent

September 15, 2008

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|--|-------------------------------------|-------------|
| Date
September 15, 2008 | EPA Reg. No./File Symbol
82572-1 | Page 5 of 6 |
| Applicant's/Registrant Name and Address
Desert King Chile
Antonio Bellet 77 Of . 401
Providencia, Santiago, Chile | Product

Quillaja Extract | |

Ingredient Quillaja saponins

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|---|-------------|-------------------|--------|---------------------|
| OPPTS 850.2100 | Avian Oral Toxicity | 46568412 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 850.2200 | Avian Dietary Toxicity | 46608110 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 850.4100 | Non-Target Plant Testing | 46608110 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 880.3550 | Immunotoxicity | 46608110 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 880.4350 | Non-Target Insect Testing | 46608110 | Desert King Chile | OWN | WAIVER REQUEST |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on White Rice | 46608111 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on Cabernet Sauvignon Grape Plants III | 46608112 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on Chardonnay Grape Plants III | 46608113 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on Cabernet Sauvignon Grape Plants I | 46608114 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on Butternut Squash Plants II | 46608115 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on Butternut Squash Plants | 46608116 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on Zucchini Plants | 46608117 | Desert King Chile | OWN | 6/7/2005 submission |

| | | |
|---|---|----------------------------|
| Signature
<i>Heather R. Bjornson</i> | Name and Title
Heather R. Bjornson, Regulatory Agent | Date
September 15, 2008 |
|---|---|----------------------------|



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|--|--|----------------------|---|--------|----------------------------|
| Applicant's/Registrant Name and Address
Desert King Chile
Antonio Bellet 77 Of . 401
Providencia, Santiago, Chile | | | Product

Quillaja Extract | | |
| Ingredient Quillaja saponins | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on Carrot Plants | 46608118
46972510 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on Cabernet Sauvignon Grape Plants II | 46608119
46972509 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on Walnut Crops | 46608120
46972506 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on Tomato Plants | 46608121 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on Tomato Plants II | 46608122
46972507 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on Lilly Bulb Plants | 46631001 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on Butternut Squash Plants III | 46608124 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Efficacy of Quillaja Extract on the Root-Knot Nematode | 46972504 | Desert King Chile | OWN | 6/7/2005 submission |
| OPPTS 810.2700 | Control of Plant Parasitic Nematodes with Quillaja Extract | 46972505 | Desert King Chile | PL | 6/7/2005 submission |
| Signature <i>Heather R. Bjornson</i> | | | Name and Title
Heather R. Bjornson, Regulatory Agent | | Date
September 15, 2008 |

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Date September 15, 2008

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82572-1

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Applicant's/Registrant Name and Address
Desert King Chile
Antonio Bellet 77 Of . 401
Providencia, Santiago, ChileProduct
Quillaja Extract

Ingredient Quillaja saponins

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|----------------------|-------------|-------------------|--------|---------------------|
| | | | Desert King Chile | OWN | 6/7/2005 submission |
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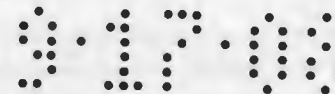
Signature

Name and Title
Heather R. Bjornson, Regulatory AgentDate
September 15, 2008



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| Date September 15, 2008 | | | EPA Reg. No./File Symbol
82572-1 | | Page 2 of 6 |
|--|----------------------|-------------|---|--------|----------------------------|
| Applicant's/Registrant Name and Address

Desert King Chile
Antonio Bellet 77 Of . 401
Providencia, Santiago, Chile | | | Product

Quillaja Extract | | |
| Ingredient Quillaja saponins | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| | | | Desert King Chile | OWN | 6/7/2005 submission |
| | | | Desert King Chile | OWN | 6/7/2005 submission |
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| Signature <i>Heather R. Bjornson</i> | | | Name and Title
Heather R. Bjornson, Regulatory Agent | | Date
September 15, 2008 |

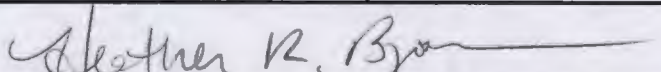


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WASHINGTON, D.C. 20460

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DATA MATRIX

| Date September 15, 2008 | | | EPA Reg. No./File Symbol
82572-1 | | Page 3 of 6 |
|--|----------------------|-------------|---|--------|----------------------------|
| Applicant's/Registrant Name and Address
Desert King Chile
Antonio Bellet 77 Of . 401
Providencia, Santiago, Chile | | | Product

Quillaja Extract | | |
| Ingredient Quillaja saponins | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| | | | Desert King Chile | OWN | 6/7/2005 submission |
| | | | Desert King Chile | OWN | 6/7/2005 submission |
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| | | | Desert King Chile | OWN | 6/7/2005 submission |
| | | | Desert King Chile | OWN | WAIVER REQUEST |
| | | | Desert King Chile | OWN | WAIVER REQUEST |
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| | | | Desert King Chile | OWN | WAIVER REQUEST |
|  | | | Name and Title
Heather R. Bjornson, Regulatory Agent | | Date
September 15, 2008 |



Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

9.17.08

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DATA MATRIX

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Applicant's/Registrant Name and Address
Desert King Chile
Antonio Bellet 77 Of . 401
Providencia, Santiago, ChileProduct
Quillaja Extract

Ingredient Quillaja saponins

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|--------------------------------------|---|---------------------------|
| Signature <i>Heather R. Bjornson</i> | Name and Title
Heather R. Bjornson, Regulatory Agent | September 15, 2008
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Applicant's/Registrant Name and Address

Desert King Chile

Antonio Bellet 77 Of . 401

Providencia, Santiago, Chile

Product

Quillaja Extract

Ingredient Quillaja saponins

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Signature

Name and Title

Heather R. Bjornson, Regulatory Agent

Date

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| Signature <i>Heather R. Bjornson</i> | | | Name and Title
Heather R. Bjornson, Regulatory Agent | | Date
September 15, 2008 |

Quillaja Extract

A Bio-Pesticide

~~For the Control Of Plant Parasitic Nematodes and Plant Parasitic Fungi~~

~~For use in Vineyards, Orchards, Field Crops, and Turf and Ornamentals~~

~~For ornamental use to control plant parasitic nematodes~~

Active Ingredient:

*Saponins of Quillaja saponaria.....8.60%

Other Ingredients.....91.40%

Total.....100.00%

*bidesmosidic derivatives of quillajic acid substituted with a trisaccharide at C-3 and an oligosaccharide in C-28

KEEP OUT OF REACH OF CHILDREN

DANGERWARNING - ADVISO PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID

If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If on skin

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

See back side for additional precautionary statements

Manufactured for:
Desert King Chile
77 Antonio Bellet, Suite 401
Providencia, Santiago
Chile

EPA Reg. No.: 82572-1
EPA Est. No.: XXXXX-XX-XX

Net Contents: XX Gallons
Batch Code: XXX

Desert King – Quillaja Extract: EPA Reg. No. 82572-1
Label Version (572); January 30, 2007 2008 September 156, 2008
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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER WARNING: Causes ~~irreversible~~ substantial but temporary eye damage. Do not get in eyes or on clothing. Harmful if swallowed or absorbed through skin. Avoid contact with skin, ~~eyes or clothing.~~ ~~Wear protective eyewear.~~ ~~Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.~~ ~~Remove and wash contaminated clothing before reuse.~~

ENVIRONMENTAL HAZARDS

~~Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.~~

~~Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Effluent System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.~~

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Protective eyewear
- Chemical-resistant gloves made of any waterproof material
- Shoes and socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

~~Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.~~

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Never apply material so as to contaminate eating or drinking area.
- Remove clothing/PPE immediately if product gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the Agency responsible for pesticide regulations.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label about personal protective equipment and the restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard. Do not enter or allow worker entry into treated areas without protective clothing during the restricted-entry interval (REI) of ~~48~~ 24 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Chemical-resistant gloves made of any waterproof material
- Protective eyewear
- Shoes and socks

NON - AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of the product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural and ornamental plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

Mixing:

~~Quillaja Extract is a water based botanical extract. It is soluble in water. Fill tank with 300 gallons of water to at least half full, then add 3 gallons recommended dosage of Quillaja Extract this product directly to the tank and continue filling. Agitation should be minimized in the tank (shut off paddle agitation if possible) to prevent foaming. —Avoid over agitating or shaking, as foaming will occur. To reduce foaming, an agricultural defoamer may be added to the tank mix. However, Quillaja Extract foam is very water soluble, will form a true solution, and should not be a concern for settling in the tank.~~

Desert King – Quillaja Extract: EPA Reg. No. 82572-1

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Apply solution within three hours of mixing. ~~To reduce foaming, add an agricultural defoamer to the tank mix.~~

3 Gallons of Quillaja Extract in 300 Gallons of water is 10,000 ppm or a 1% Solution of Quillaja Extract in water.

Compatibility:

Quillaja Extract is a water soluble botanical extract. It is physically compatible with most water based pesticides and liquid fertilizers providing the pH of the final solution is in a pH range of 3 to 8. Quillaja Extract is compatible with most common pesticides and can be tank mixed with fungicides, insecticides, herbicides, fertilizers or other nematocides. Do not apply Quillaja Extract with any other product before testing for physical and chemical compatibility. To determine compatibility, pour the recommended proportions of the products into a suitable container, mix and wait for 30 minutes. If product remains mixed, it is considered physically compatible.

However, do not mix with products that will render a final pH above 8. Not all tank mix combinations have been tested with this product. If compatibility of this product with another product is unknown, the mixture should be tested on a small scale.

Read and carefully observe the most restrictive of the labeling limitations and precautions of precautionary statements and all other information on all product labels used in the tank mix. This product has properties similar to wetting agents and may enhance activity of some products as a wetting agent. ~~Not all tank mix combinations have been tested with this product.~~

Compatibility:

Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures.

Quillaja Extract is physically compatible with most water based pesticides and liquid fertilizers providing the pH of the final solution is below a pH of 8 and above a pH of 3. To determine physical compatibility of this product with other products, pour the recommended proportions of the products into a suitable container, mix and wait for 30 minutes. If product remains mixed, it is considered physically compatible. Apply all mixed material within 2-3 hours per application.

Application Methods: Consider the high solubility of this product when choosing a method of application and timing.

For Powdery Mildew

~~Apply by ground equipment only in sufficient water (50 gallons per acre minimum) to ensure complete and thorough coverage of foliage and/or crop. Contact of the disease organisms is essential for control.~~

Foliar spray application (for powdery mildew): Apply by ground equipment to ensure complete and thorough coverage of foliage and/or crop. Contact of the disease organisms is essential for curative control. ~~Fill spray tank with to then recommended dosage of.) To reduce foaming, an agricultural defoamer may be added to the tank mix. However, , and~~

For Root Rot and Nematodes Ground spray application (for nematodes and root rot): After area to be treated has been irrigated to field capacity, apply with a band or broadcast type sprayer, such as flat-fan or hollow cone nozzle tip system, to the soil surface. After application has been made it will be necessary to water with either drip, above ground sprinklers or reduced amount of furrow irrigation. Do not over irrigate following application of this product. Do not use flood irrigation to apply this product into the ground. Over irrigation will move the desired concentration of the product too quickly past the targeted root zone.

For ground sprayer application in orchards or around trees, begin application next to the tree trunk and spray at least 50% of soil area or the area under the canopy of the tree, whichever is greatest.

Shank injection application (for nematodes): After area to be treated has been irrigated to field capacity, apply by shank injection to areas where roots are present. Use a sufficient number of injectors to cover area to be treated. If shank application is applied at the root zone, minimal irrigation is required to assure that product covers root zone.

Chemigation application (for nematodes and root rot): Apply Quillaja Extract through the following types of systems. Do not apply this product through any other type of irrigation system.

- Low volume (ground or underground) drip, drip tape, strip tubing, micro-jet sprinklers, mini-sprinklers;
- Sprinkler including center pivot, lateral move, end tow, side (wheel) roll, solid set, or hand move;
- Furrow.

Check irrigation system and emitters to ensure all systems are operating normally before injecting Quillaja Extract. Lack of effectiveness or crop injury can result from non-uniform distribution of treated water.

If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers, chemigation experts or the Distributor of this product.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place. In addition, check local and state regulations regarding pesticide injection into public water systems.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Maintain the system's operating pressure low enough to prevent fogging and/or misting during applications. Inject Quillaja Extract into the irrigation system after the filter(s) or shut off the automatic back flush system in order to avoid back flushing of treated water.

Systems using a gravity flow pesticide dispensing system must meter the product into the water at the head of the field and downstream of the hydraulic discontinuity, such as a drop structure or weir box, to decrease potential for water source contamination from backflow if water flow stops.

Systems using a pressurized water and pesticide injection system must meet the following requirements:

- The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
- The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of material that are compatible with pesticide and capable of being fitted with a system interlock.

It is highly recommended that the soil be irrigated to field capacity (down to two feet of soil) before pesticide application. For best results, inject Quillaja Extract into the irrigation line in the last quarter of the irrigation time. Continue irrigation until all lines are flushed. Maintain irrigation for enough time to assure this product has penetrated down into the targeted root zone. Do not over irrigate after applying this product. If excessive watering occurs immediately following application, this product may move down past the desired root zone due to its high water solubility. Do not irrigate for at least 24 hours

following application of this product. Pest injury to the crop or lack of effectiveness in growth response may result from uneven distribution of this product during application.

[LG4]

Do not allow air in the line prior to injecting Quillaja Extract. The product's density will cause swelling of the line due to foam formation and prevent uptake of material. If a pesticide supply tank is used, follow directions listed under "Mixing" above. fill with to and then), and There generally will be some level of foam at the base of the wetted area until it dissolves (usually within 30 minutes after application, depending on temperature and amount of water following application).

If applied in heavy rainfall areas, avoid application during rain or when rain is forecasted within the next 24 hours that may exceed movement of this product past targeted root zone.

Do not apply when wind speed favors drift beyond the areas intended for treatment

Application:

Quillaja Extract may be applied using ground equipment with a band sprayer, soil fertilizer shanks, injected through drip irrigation or through above ground sprinkler systems.

Application Rates for Control of Nematodes

To control/suppress plant parasitic nematodes, apply Quillaja Extract to the full irrigated zone. For row crops, the irrigated zone is 30-50% of the row area. For orchards or around trees, apply from tree trunk to drip-line to cover at least 50% of soil area or the area under the canopy of the tree, whichever is greatest. Single applications should be made in the spring just prior to or during root flush, and again in the fall after harvest. For best results, multiple applications may be made in the spring, followed by a single application in the fall after harvestes. ~~For row crops, the irrigated zone is 30-50% of the row area. For orchards or around trees, apply from tree trunk to drip-line to spray at least 50% of soil area or the area under the canopy of the tree, whichever is greatest.~~ For specific crop instructions, see Table 1 below.

| Crop | <u>Remarks</u> |
|--|--|
| <p><u>Berries:</u>
 <u>Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry),</u>
 <u>Blueberry, Cranberry, Currant, Elderberry,</u>
 <u>Gooseberry, Huckleberry, Loganberry,</u>
 <u>Raspberry (black and red)</u></p> <p><u>Citrus:</u>
 <u>Calamondin, Citrus citron, Citrus hybrids,</u>
 <u>Grapefruit, Kumquat, Lemon, Lime,</u>
 <u>Mandarins, Orange (sour and sweet),</u>
 <u>Pummelo</u></p> <p><u>Grapes (raisin, table, wine)</u></p> <p><u>Nut Crop:</u>
 <u>Almond, Beech nut, Brazil nut, Butternut,</u>
 <u>Cashew, Chestnut, Cinquapin, Filbert,</u>
 <u>Macadamia, Pecan, Walnut (black and</u>
 <u>English)</u></p> <p><u>Pome Fruit:</u>
 <u>Apple, Crabapple, Loquat, Mayhaw, Pear</u>
 <u>(including oriental pear), Quince</u></p> <p><u>Stone Fruit:</u>
 <u>Apricot, Cherry (sweet or tart), Nectarine,</u>
 <u>Peach, Plum, Plumcot, Prune</u></p> | <p>On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p><u>For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.</u></p> |

| | |
|--|--|
| | <p>For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.</p> |
|--|--|

Cole Crops:

Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables:

Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables:

Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables:

Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Strawberry

Apply 1-7 days preplant to the planting zone. Apply centered on the top of the row on pre-wetted soil. Follow with water to assure penetration of the product into the root zone.

On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.

On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.

For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.

| | |
|--|--|
| <p><u>Bulb Vegetable:</u>
 <u>Garlic, Leek, Onion (including dry bulb, green and Welch), Shallot</u></p> <p><u>Root and Tuber Vegetables:</u>
 <u>Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Ginseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)</u></p> <p><u>Ornamentals:</u>
 <u>Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals</u></p> | <p><u>Apply prior to planting to row area to be planted. Apply centered on the top of the row on pre-wetted soil. Follow with water to assure penetration of the product into the root zone.</u></p> <p><u>On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</u></p> <p><u>On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</u></p> <p><u>For best results, multiple applications may be made at a rate of 2 quarts/acre in 50-100 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) every 7-14 days for up to 10 weeks.</u></p> |
| <p><u>Turfgrass</u>
 <u>Ornamental lawns,</u>
 <u>Golf courses,</u>
 <u>Sod farms</u></p> <p><u>For control of <i>Anguina pacifica</i> nematode only.</u></p> | <p><u>Apply 9 fl.oz. in 3-7 gallons water per 1,000 sq.ft. (equivalent to 3 gallons in 130-300 gallons water per acre) using a sprayer with a pressure nozzle tip applicator sufficient to penetrate into the lower part of the turf leaves where <i>Anguina pacifica</i> nematode galls are formed. Do not exceed a concentration of 1.5% solution of Quillaja Extract in any application.</u></p> <p><u>Repeat applications every 5-10 days. Additional applications to break the life cycle of the nematode should be repeated 2-4 times within 60 days to significantly reduce this pest problem in one season.</u></p> <p><u>Do not water turfgrass for at least 12 hours following application of Quillaja Extract. Quillaja Extract is water soluble and does not require additional water application through sprinkler following application.</u></p> |
| <p><u>Strawberry</u></p> | <p><u>Apply 3-7 days preplant to the planting zone. Apply centered on the top of the row on pre-wetted soil.</u></p> |

| | |
|--|--|
| | <p>Follow with water to assure penetration of the product approximately 2-4 inches deep into the soil.</p> <p>On heavily infested soils, apply 1-2 gallons in 200 gallons finished spray solution per acre on the first application.</p> <p>On light to moderately infested soils, apply 1.5 gallons in not more than 150 gallons finished spray solution per acre.</p> <p>For best results, follow with sequential applications of 1 quart/acre (in not more than 25 gallons finished spray solution) every 4-6 weeks.</p> <p>On heavily infested soils, apply 3 gallons in 300-600 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> <p>On light to moderately infested soils, apply 1.5 gallons in 150-300 gallons water per acre (to achieve a concentration of 5,000-10,000 ppm) in a single application.</p> |
|--|--|

Table 1

| Quillaja Extract
Rate per Acre | | | |
|--|--------------------|----------------------------|---|
| CROP | INITIAL
DOSAGE | SEQUENTIAL
APPLICATIONS | COMMENT |
| Grapes | 1.5—3.0
gallons | 1.0 quart | On heavily infested soils apply at least 1.0 3.0 gal/acre on the first application. Use highest rate when nematode count is severe according to common practice. On light to moderately infested soils apply 1.5 gal/acre. For best results follow first application with sequential applications of one quart/acre every 7-14 days, for up to 8-10 10 weeks. |
| Citrus | 1.5—3.0
gallons | 1.0 quart | On heavily infested soils apply at least 1.0 3.0 gal/acre on the first application. On light to moderately infested soils apply 1.5 gal/acre. For best results follow first applications with sequential applications of one quart/acre every 7-14 days, for up to 4-6 6 weeks. |
| Pome Fruit:
Apple, Loquat,
Mayhaw, Pear,
Quince

Stone Fruit:
Apricot, Cherry,
Nectarine, Peach,
Plum, Prune

Nut Crop:
Almond, cashew,
macadamia,
pecan, walnut | 1.5—3.0
gallons | 1.0 quart | On heavily infested soils apply at least 1.0 3.0 gal/acre on the first application. On light to moderately infested soils apply 1.5 gal/acre. For best results follow first applications with sequential applications of one quart/acre every 7-14 days, for up to 4-6 6 weeks. |

| Quillaja Extract
Rate per Acre | | | |
|--|--------------------|----------------------------|---|
| CROP | INITIAL
DOSAGE | SEQUENTIAL
APPLICATIONS | COMMENT |
| Strawberry | 1.5—3.0
gallons | 1.0 quart | Apply 3 to 7 days preplant into the planting zone. If applying with ground equipment apply centered on the top of the row on pre-wetted soil at a dilution between 10,000 (1%) to 5,000 (½%) parts per million (PPM) or between 1 and a maximum of 2 gallons per 200 gallons of water and follow with water to assure penetration of the product at least 2-4 inches deep into the soil. On low to moderate infested soils apply 1.5 gallons per acre at planting followed by sequential applications of 1 quart/acre every week for 4-6 weeks. |
| Fruiting Vegetables:
eggplant, peppers, tomatillo, tomato

Cucurbit Vegetables:
cucumber, gherkin, edible gourd, melon, pumpkin, squash, watermelon

Leafy Vegetables:
celery, endive, lettuce, purslane, spinach, swiss chard

Cole Crops:
broccoli, cabbage, | 3.0
gallons | 1.0 quart | Apply 1 to 7 days prior to planting to area to be planted. Follow up with sequential applications of 1 quart/acre every week for 4-6 weeks. |

| | | | |
|--|---------------------------|------------------------------------|---|
| kale, kohlrabi,
mustard greens,
mustard spinach,
rape greens | | | |
| Quillaja Extract
Rate per Acre | | | |
| CROP | INITIAL
DOSAGE | SEQUENTIAL
APPLICATIONS | COMMENT |
| Bulb Vegetable:
garlic, leek, onion,
shallot | 3.0
gallons | 1.0 quart | Apply prior to planting to row
area to be planted. Not for
control of Foliar Nematodes.
Follow up with sequential
applications of 1 quart/acre
every week for 4–6 weeks. |
| Root and Tuber
Vegetables:
arrowroot,
artichoke, beet,
burdock, canna,
carrot, ginger,
gingseng,
horseradish,
potato, radish,
turnip, yam | 3.0
gallons | 1.0 quart | Apply prior to planting to row
area to be planted. Follow
up with sequential
applications of 1 quart/acre
every week for 4–6 weeks. |
| Ornamentals
Bulbs | 3.0
gallons | None | Apply prior to planting. |

Application Rates for Control of Fungi

For control/suppression of ~~pathogenic fungi~~, apply as described below in Table 2

For control/suppression of **POWDERY MILDEW** in the following field and greenhouse-grown crops, apply 1-4 pints Quillaja Extract per acre as a foliar spray in 50-100 gallons water per acre (equivalent to 0.5-1.5 fl.oz. in 1-2 gallons water per 1,000 sq.ft.) every 7-10 days depending on severity of infection. A surfactant is not necessary, but the addition of a wetting agent, such as Yucca Ag-Aide™, may increase efficacy. Quillaja Extract may be tank mixed with Sterol Inhibitor type fungicides.

Berries and Small Fruits: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Grape (raisin, table, wine), Huckleberry, Kiwifruit, Loganberry, Raspberry (black and red), Strawberry

Bulb Vegetable: Garlic, Leek, Onion (including dry bulb, green and Welch), Shallot

Cereal Grains: Barley, Buckwheat, Corn, Millet, (pearl and proso), Oats, Popcorn, Rice, Rye, Sorghum (milo), Teosinte, Triticale, Wheat, Wild rice

Cole Crops: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables: Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Legume Vegetables (succulent or dried): Bean (*Lupinus*, *Phaseolus* and *Vigna* spp.), Broad bean, Chickpea, Guar, Jackbean, Lablab bean, Lentil, Pea (*Pisum* spp.), Pigeon pea, Soybean, Sword bean

Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)

Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince

Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Gingseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune

Subtropical Fruits: Banana, Date, Mango, Papaya, Pineapple

Additional crops: Hops, Mint (peppermint, spearmint), Tobacco

Herbs and Spices: Allspice, Angelica, Anise, Annatto, Balm, Basil, Borage, Burnet, Camomile, Caper buds, Caraway, Cardamom, Cassia, Catnip, Celery seed, Chervil, Chive, Cinnamon, Clary, Clove buds, Coriander, Coriander, Costmary, Culantro, Cumin, Curry, Dill, Fennel, Fenugreek, Grains of paradise, Horehound, Hyssop, Juniper berry, Lavender, Lemongrass, Lovage, Mace, Marigold, Marjoram, Mustard, Nasturtium, Nutmeg, Parsley, Pennyroyal, Pepper, Poppy seed, Rosemary, Rue, Saffron, Sage, Savory, Sweet bay, Tansy, Tarragon, Thyme, Vanilla, Wintergreen, Woodruff, Wormwood

Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals

Turf: Ornamental lawns, golf courses and sod farms

For control/suppression of **PHYTOPHTHORA** and **PYTHIUM ROOT ROT** in the following field and greenhouse-grown crops, apply 2-4 quarts Quillaja Extract in 200 gallons water per acre (equivalent to 1.5-3 fl.oz. in 5 gallons water per 1,000 sq.ft.) to achieve a concentration of 2,500-5,000 ppm. Apply in early spring and fall, prior to root flush when soil temperatures are optimum for root infection. Apply to the entire root zone

following, or at the end of, an irrigation cycle For best results, repeat application every 7 days, for up to 6 weeks. A surfactant is not necessary, but the addition of a wetting agent, such as Yucca Ag-Aide™, may increase efficacy. Quillaja Extract may be tank mixed with Sterol Inhibitor type fungicides.

Berries and Small Fruits: Blackberry (including boysenberry, dewberry, marionberry, olallieberry, youngberry), Blueberry, Cranberry, Currant, Elderberry, Gooseberry, Grape (raisin, table, wine), Huckleberry, Kiwifruit, Loganberry, Raspberry (black and red), Strawberry

Citrus: Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarins, Orange (sour and sweet), Pummelo,

Cole Crops: Broccoli (including Chinese and raab), Brussels sprouts, Cabbage (including Chinese), Cauliflower, Collards, Kale, Kohlrabi, Mizuna, Mustard greens, Mustard spinach, Rape greens

Cucurbit Vegetables: Chayote, Chinese waxgourd, Citron melon, Cucumber, Gherkin, Edible gourd, Momordica spp. (including balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (including cantaloupe, casaba, crenshaw, golden pershaw, honeydew, honey balls, mango, Persian, pineapple, Santa Claus, and snake), Pumpkin, Summer squash (including crookneck, scallop, straightneck, vegetable marrow and zucchini), Watermelon, Winter squash (including acorn, butternut, calabaza, hubbard, and spaghetti)

Fruiting Vegetables: Eggplant, Groundcherry, Pepino, Pepper (including bell, chili, cooking, pimento and sweet), Tomatillo, Tomato

Leafy Vegetables: Amaranth, Arugula, Cardoon, Celery (including Chinese celery), Celtuce, Chervil, Edible chrysanthemum, Corn salad, Cress (garden and upland), Dandelion, Dock (sorrel), Endive (escarole), Fennel, Lettuce (head and leaf), Orach, Parsley, Purslane (garden and winter), Radicchio, Rhubarb, Spinach (including New Zealand and vine), Swiss chard

Nut Crop: Almond, Beech nut, Brazil nut, Butternut, Cashew, Chestnut, Cinquapin, Filbert, Macadamia, Pecan, Walnut (black and English)

Pome Fruit: Apple, Crabapple, Loquat, Mayhaw, Pear (including oriental pear), Quince

Root and Tuber Vegetables: Arrachacha, Arrowroot, Artichoke, Beet (garden and sugar), Burdock, Canna, Carrot, Cassava (bitter and sweet), Celeriac, Chayote, Chervil, Chicory, Chufa, Dasheen, Ginger, Gingseng, Horseradish, Leren, Parsley (turnip rooted), Parsnip, Potato, Radish, Rutabaga, Salsify, Skirret, Sweet potato, Tanier, Turmeric, Turnip, Yam (bean and true)

Stone Fruit: Apricot, Cherry (sweet or tart), Nectarine, Peach, Plum, Plumcot, Prune

Additional crops: Avocado, Kiwifruit

Ornamentals: Bare root, container, bedding and flowering stock, cut flowers, nursery and landscape, potted flowering, shade and flowering trees, woody ornamentals

Table-2

| QUILLAJA EXTRACT | |
|-------------------------|--|
| Rate Per Acre | |

| Crop | Pathogen | Dosage | Comments [LG9] |
|------------|---|---------|---|
| Grapes | Powdery Mildew, | 1—4 pts | Apply as a foliar spray in 50 to 100-gallons water per acre every 7 to 10 days depending on severity of infection. Do not tank mix with sulfur products. May cause leaf burn if sulfur is present. Do not apply within 7 days of a sulfur application. You may tank mix with Sterol Inhibitor type fungicides. |
| Strawberry | Powdery Mildew | 1—4 pts | Apply as a foliar spray in 50 to 100-gallons water per acre every 7 to 10 days depending on severity of infection. Do not tank mix with sulfur products. May cause leaf burn if sulfur is present. Do not apply within 7 days of a sulfur application. |
| Avocado | Root Rot, <i>Phytophthora cinnamomi</i> | 2—4 Qts | Apply 1 to 6 times per season into the full irrigated root zone. Apply in early Spring and Fall prior to root flush when soil temperatures are optimum for root infection. For best results apply every 7 days, for up to 6 weeks. If applying with a ground sprayer apply to the entire root zone area directly under the tree. [LG10] |

Application Rates to Enhance Plant Growth and Yield

Under good growing conditions, absent of plant parasitic nematodes or plant parasitic fungi, Quillaja Extract is beneficial to plant growth and yield as described below in table 3.

Table 3

| QUILLAJA EXTRACT | | | |
|------------------|--|----------------------|---|
| Rate Per Acre | | | |
| Crop | Benefit | Dosage Rate per Acre | Comment |
| Grapes | Increased Fruit Yield and Root Development | 1—2 quarts | Apply at root flush followed by 2—4 applications at 7—14 day intervals. |
| Citrus | Increased Root Development | 1—2 gallons | Apply 1—2 gallons/acre at root flush followed by 2 quarts/acre every 14 |

| | | | |
|-------------------|----------------------------|----------|--------------------------------------|
| | | | days for 4-6 weeks. |
| Strawberry | Increased Root Development | 2--4 pts | Apply every 14 days for 8--10 weeks. |

Application Methods

~~Quillaja Extract may be applied using ground equipment with a band sprayer, soil fertilizer shanks, injected through drip irrigation or through above ground sprinkler systems. This product should be applied after soil is irrigated to field capacity.~~

~~**Ground application:** Apply with a band or broadcast type sprayer, such as flat-fan or hollow cone nozzle tip system, on the surface of the area to be treated. After application has been made it will be necessary to water with either drip, above ground sprinklers or reduced amount of furrow irrigation. Do not over irrigate following application of this product. Do not use flood irrigation to apply this product into the ground. Over irrigation will move the desired concentration of the product too quickly past the targeted root zone.~~

~~For ground sprayer application in orchards or around trees, begin application next to the tree trunk and spray at least 50% of soil area or the area under the canopy of the tree, whichever is greatest.~~

~~**Shank Injection.** Apply by shank injection to areas where roots are present. Use a sufficient number of injectors to cover area to be treated. If Shank application is applied at the root zone, minimal irrigation is required to assure that product covers root zone.~~

~~**Chemigation applications:**~~

~~Apply Quillaja Extract through low pressure irrigation equipment (including drip, mini-sprinklers, micro-jet sprinklers and strip tubing). Do not apply this product through any other type of irrigation system.~~

~~The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.~~

~~The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.~~

~~The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.~~

~~The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.~~

~~The irrigation line or water pump must include a functional pressure switch which will stop the water pump when the water pump motor stops.~~

~~The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.~~

~~Systems must use a metering pump such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of material that are compatible with pesticide and capable of being fitted with a system interlock.~~

~~Do not apply when wind speed favors drift beyond the areas intended for treatment~~

~~A pesticide supply tank is not necessary since this product is 100% water soluble. If a pesticide supply tank is used, dilute the product with just enough water to assure an application concentration at the end of the irrigation line between 5,000 and 10,000 ppm which corresponds to 0.5% and 1% respectively. Final dilution of product should be between 1 and 2 gallons of product for every 200 gallons of irrigation water used. Normally use between 1 and a maximum of 2 gallons per 200 gallons of irrigation water.~~

~~Do not allow air in the line prior to injecting Quillaja Extract or density of Quillaja Extract will cause swelling of the line due to foam and prevent uptake of material. If a pesticide supply tank is used, add Quillaja Extract after water at least half full in the tank to prevent excessive foaming. Agitation should be minimized in the supply tank (shut off paddle agitation if possible to prevent foaming). Quillaja Extract foam is very water soluble, will form a true solution should not be a concern for settling in the tank. Maintain the system's operating pressure low enough to prevent fogging and/or misting during applications. Inject Quillaja Extract into the irrigation system after the filter(s). In Low Volume (Drip Irrigation), begin normal irrigation and make sure all emitters are working properly. For best results, inject into the irrigation line in the last quarter of the irrigation time at a rate that assures a concentration between 5,000 and 10,000 ppm at the emitter. As a general rule, do not apply more than 200 gallons of water per 1 gallon of this product.~~

~~Continue irrigation until all the lines are flushed and then maintain irrigation for enough time to assure this product has penetrated down into the targeted root zone (at least 30 minutes). Do not over irrigate after applying. If excessive watering occurs immediately following application, this product may move down past the desired root zone due to its high water solubility. Do not irrigate following application of this products for at least 24 hours.~~

~~If applied in heavy rainfall areas, avoid application during rain or when rain is forecasted within the next 24 hours that may exceed movement of this product past targeted root zone. Pest injury to the crop or lack of effectiveness in growth~~

~~response may result from uneven distribution of this product during application. Consider the high solubility of this product when choosing a method of application and timing.~~

~~It is highly recommended that the soil be wetted first with irrigation system to wet the soil profile and eliminate any dry areas under the irrigated area down to two feet of soil, thereafter Quillaja Extract should be applied during the last few hours of the irrigation, followed with enough clean out water run through the system to remove Quillaja Extract. There generally will be some level of foam at the base of the wetted area until it dissolves (usually within 30 minutes after application, depending on temperatures and amount of water following application.~~

~~Lack of effectiveness of Quillaja Extract or Crop Injury can result from non-uniform distribution of treated water.~~

~~Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.~~

~~A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.~~

~~If you have any questions about calibration of this product, you should contact State Extension Service specialists, equipment manufacturers, chemigation experts or the Distributor of this product.~~

~~Posting is not necessary following application of this product when the label is accurately followed.~~

Non-Agricultural uses: Turfgrasses

| Crop | Pest | Dosage
Quillaja Extract |
|---|--|--|
| TURFGRASSES
For use on golf
courses and sod
farms | <i>Anguina pacifica</i>
nematode only | 9.0 fl oz./1000 sq.ft.
or
3.0 Gallons/Acre |

~~Apply specified dosage in a minimum of 3-7 Gallons of water per 1000 sq.ft. (approximately 150-300 Gallons per Acre) with a pressure nozzle tip applicator sufficient to penetrate into the lower part of the turf leaves where *Anguina pacifica* nematode galls are formed.~~

~~Quillaja Extract is water soluble and does not require additional water application through Sprinkler following application. Repeat application of Quillaja Extract every 5-10 days following first application. Additional applications to break the~~

~~life cycle of the nematode should be repeated 2-4 times within 60 days to significantly reduce this pest problem in one season.~~

~~Do not water turf or sod for at least 12 hours following application of Quillaja Extract.~~

~~Do not exceed a concentration of 1.5 % solution of Quillaja Extract in any application.~~

~~Do not apply Quillaja Extract with any other product before testing for physical and chemical compatibility.~~

~~Do not cause excessive agitation of material to avoid foaming of Quillaja Extract.~~

~~Do not apply Quillaja Extract through sprinklers or any other irrigation system that exceed the desired concentration of 1-1.25% solution of Quillaja Extract product in water.~~

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in cool dry area.

Pesticide Disposal: Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Un-Refillable Container. Do not refill or reuse this container. Triple rinse (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

LIMITED WARRANTY

Desert King Chile warrants that this product conforms to the chemical description on the label and is reasonable fit for the purposes set forth in the Complete Directions for Use label booklet ("Directions") when used in accordance with those Directions under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

[] indicate optional text

Optional Label Claims:

- Controls and/or Suppresses certain foliar diseases such as Powdery Mildew(s)
- Suppresses [Nematodes], [Powdery Mildew]
- For use also on Vegetable Crops Such as: Carrots, Peppers, Tomatoes, Broccoli, Squash, and Beets.